Expressive writing in dialysis patients

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PART A: Main Research Project

Expressive writing in dialysis patients

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Abstract

Previous research has identified that distress is common in patients with kidney failure who undergo dialysis treatment and that this is associated with poor outcomes (Chilcot, Davenport, Wellsted, Firth, & Farrington, 2011a). Few studies have examined the effectiveness of psychological interventions aimed at improving psychological distress in this patient group. Expressive Writing (EW) is a therapeutic technique that typically involves participants writing about a stressful or traumatic event for 15-20 minutes on 3-5 consecutive days (Pennebaker & Buell, 1986) and has been associated with improvements in psychological (e.g. well-being) and clinical (e.g., immune function) outcomes in several populations, including breast cancer patients (Craft, Davis & Paulson, 2012). The aims of the current study were to establish feasibility of using EW with this patient group. This was done by identifying the factors associated with distress, gauging acceptability and safety of the intervention, recording recruitment and retention rates and by establishing its potential clinical efficacy. The study consisted of two phases; a screening phase which used a cross-sectional questionnaire survey of 97 patients, and a trial phase which randomised 30 patients into two groups (EW or control), with a 3-month follow-up. Results indicated that self-reported symptoms of fatigue and pain, and illness perceptions predicted a significant amount of variance (35%) in distress, above demographic and clinical variables. The EW intervention was found to be feasible in terms of uptake and agreement to randomisation. However, retention rates were lower than some previous EW studies suggesting that modifications are needed to the writing protocol in order to increase adherence. Despite poor retention, results indicated improvements in distress (d=0.23) and systolic blood pressure (d=0.71) for the EW group, when compared to the control group at follow-up. This suggests that, with modification, EW may be cost effective way to reduce distress in dialysis patients. These findings are discussed with reference to limitations and future research, as well as implications for clinical practice.

1.0 INTRODUCTION

1.1 Kidney Disease

The kidneys are a pair of vital bodily organs that perform many functions essential to life. Their main purpose is to sift blood and filter out metabolic waste products, excess salt and water. They also serve to regulate the body's level of certain chemical substances (e.g., sodium, phosphorus and potassium) and release important hormones which stimulate the production of red blood cells, regulate blood pressure and help maintain calcium for bones. Kidney disease occurs when nephrons (small units inside the kidneys) lose their filtering capacity. In most cases, this happens as a result of another underlying physical disorder, such as diabetes or high blood pressure. These conditions cause structural abnormalities, which lead to a decrease in kidney functioning.

An international classification system was developed by the US Kidney Foundation in their Kidney Disease Outcomes Quality Initiative (Eknoyan & Levin, 2002). This defines five stages of kidney disease based on estimated Glomerular Filtration Rate (eGFR), a numerical rating to indicate how efficient the kidneys are at filtering wastes from the blood. This is calculated using the four-variable MDRD (Modification of Diet in Renal Disease) formula based on a patient's serum creatinine level, age, sex and ethnicity, and has been endorsed by the Department of Health for England (UK Renal Association, 2011). A person whose eGFR remains below 60 for at least 3 months is considered to have Chronic Kidney Disease (CKD). According to the K/DOQI guidelines, an eGFR of >90 with other evidence of kidney damage characterises stage 1; 60-90 indicates a slight decrease in functioning and characterises stage 2; 30-69 indicates a moderate decrease and characterises stage 3; and 15-30 indicates a severe decrease and characterises stage 4. Finally, an eGFR of less than 15 implies established kidney failure. At this stage, the reduction in kidney functioning is so severe that it is not compatible with life and individuals are usually diagnosed as having "End Stage Kidney Failure" (ESKF) or "End Stage Renal Disease" (ESRD). This coincides with excess fluid, metabolic toxins and electrolytes rapidly accumulating in blood and bodily tissues. These substances must be removed by another method if life is to be sustained and means patients must undergo renal replacement therapy (or 'RRT') in order to survive.

Diseases of the kidney have assumed epidemic proportions and are among the leading causes of death in the industrialised world (Eknoyan et al, 2004). According

to the 2010 Global Burden of Disease study, CKD was ranked 18th in the list of causes of total number of global deaths during that year (Lozano, Naghavi & Foreman, 2013), and is thought to affect approximately 10% of the global population (e.g., Coresh et al, 2005; Che, Wildman & Gu, 2005). Although this figure is alarming in itself, the high co-occurrence of CKD with cardiovascular diseases and diabetes mellitus means that this figure may in fact be a severe underestimation of the total global prevalence (Jha et al, 2013).

1.2 Renal Replacement Therapy (RRT)

In general, choice of RRT treatment modality tends to be influenced by non-medical factors including the preferences of the patient and provider, and judgments about which modality will have the most favourable outcomes on adherence and quality of life (QOL; Christensen & Ehlers, 2002). There are three RRT options available: transplant and two types of repetitive dialysis known as haemodialysis (HD) and peritoneal dialysis (PD).

1.2.1 Transplant

In the late 1960s transplant became a viable option for RRT. At present, approximately 28% of ESRD patients have a functioning renal graft which comes from a brain dead or living donor (USRDS, 1999). For most patients, the transition from pre to post-transplant means increased independence from health providers and more responsibility for managing one's own treatment e.g., monitoring immunosuppressive status.

1.2.2 Haemodialysis (HD)

HD treatment involves a vascular connection being made between an artificial kidney (dialyzer) and the patient, usually through an arteriovenous fistula permanently placed in the patient's forearm. During the treatment process, blood travels through tubes into the dialyzer machine, which acts like a kidney by filtering the blood. The cleaned blood then flows through another set of tubes back into the body. This process is typically performed three times a week by a nurse or a trained technician in a clinic setting with each session lasting approximately three to four hours (NIDDK, 2002), although it is recommended that suitable patients should be offered the choice between home and hospital-based HD (NICE, 2002).

1.2.3 Peritoneal dialysis (PD)

PD treatment involves the patient taking a more active role and is usually performed by the patient at their residence (Kusiak, Dixon & Shah 2005). The most common

form is continuous ambulatory peritoneal dialysis (CAPD). In this procedure, a permanent catheter is surgically implanted into the abdomen. A sterile tube connects the catheter to a bag of dialysis solution which is elevated to allow flow to the peritoneal cavity. Once this is completed, the bag is hidden away under the patient's clothing. Over the next 4-8 hours, the patient's blood filters through the peritoneal membrane leaving toxins and excess fluid in the solution. After this phase is completed, the bag is lowered and the used solution is drained back into the bag. This solution is then discarded ready for the procedure to begin again. Each treatment takes one hour and is repeated 3 to 6 times each day (Christensen and Ehlers, 2002).

1.2.4 Prevalence of RRT

Transplant remains the modality of choice for patients considered fit for major surgery and chronic immunosuppression (UK Renal Association, 2013). However, a report by Grassman, Gioberge, Moeller and Brown (2005) found that, due to a shortage of donors and a high transplant rejection rate, HD has become the most commonly used modality of RRT across the world. This report details the outcome of a survey collecting demographic information from 122 countries with established dialysis programmes. It revealed that the total number of patients worldwide on some form of dialysis treatment in 2005 was approximately 1.4 million, and that the number was growing at an annual rate of 7%. However, the incidence and prevalence of patients treated with dialysis varies substantially across countries and regions, with a disproportionately high percentage (about 80%) of patients living in developed countries (White, Chadman, Jan, Chapman & Cass, 2008). The main factors thought to be contributing to the rising number of dialysis patients include; universal ageing in population, increasing access of younger patients to treatment in countries where access was previously limited, and growing numbers of people diagnosed with type 2 diabetes (El Nahas & Bello, 2005). Currently, the RRT population in the UK is around 40,000, with around 25,000 on dialysis in total (Gilg, Castledine & Fogarty, 2010).

1.3 Psychological Impact of Dialysis

"…as long as the struggle for survival was the main issue, emotional problems were suppressed."

Belding Scribner as cited in Levy (1996)

Contrary to the above quote, it is now well recognised that physical illness can result in psychological distress, particularly in the case of chronic illness. It has been suggested that about 20-25% of patients suffering from chronic medical problems also experience clinically significant psychological symptoms (White, 2001).

Since the 1960s, when HD first became a practical treatment for kidney failure, it has vastly increased the survival rate of patients with CKD. Clinicians have also learnt a lot about how to minimize the side effects to make it a more tolerable and effective treatment. However, it remains a complicated and inconvenient therapy that requires a coordinated effort from a multi-disciplinary health care team. Furthermore, there are a number of physical and emotional challenges associated with dialysis treatment which can inflict considerable amounts of stress on patients' lives. Some of these will be outlined below.

1.3.1 Restrictive lifestyle

ESRD imposes restrictions on all areas of life. Firstly, patients must incorporate the dialysis treatment procedure into their daily lives. Since an average HD session takes approximately 3-5 hours and takes place three times a week, it consumes a significant proportion of a patients' time. The process of treatment adjustment has been characterised by Thorne (1993) as 'negotiation' and encompasses a number of limitations in lifestyle. Polaschek (2003) interviewed a group of male Caucasian dialysis patients who discussed these limitations and highlighted particular difficulties with organising travel and holidays. They explained how the relaxation and freedom usually connected with holidays is contradicted by the relentless requirements of the dialysis regime. Patients also talked about a sense of 'ongoingness' which meant they felt frustrated and pressurised to maximise their free time when off dialysis.

Dialysis patients also have to adhere to a controlled diet, limit their fluid intake and follow a complex regime of medications, particularly when they suffer from one or more co-morbidities. Dietary restrictions are considered by many to be most difficult component of treatment for ESRD patients (Khalil et al, 2010). The main dietary restrictions prescribed include protein, potassium, sodium, calcium and phosphorus (Oka & Chaboyer, 1999). If these substances are not restricted, patients risk elevations in potassium and sodium concentration and fluid overload, which can have serious long-term consequences (Kutner, 2001). The medication regime may consist of up to 12 different drugs, which facilitate the management of blood pressure, anaemia, abnormalities of mineral metabolism and other problems related

to co-morbidities. HD recipients also have to restrict their salt and fluid intake, which forms another challenging element of treatment (Christensen & Moran, 1998). Patients are also instructed to ingest no more than 1 L of fluid per day due to irregularity of fluid clearance achieved by dialysis treatments. Failing to adhere to this could potentially result in cardiac failure, hypertension, pulmonary oedema and premature death (Leggat et al, 1998).

Maintaining any kind of normality in the face of this commitment to treatment is difficult and demands radical rearranging and modification of routine activities (Curtin, Mapes, Petillo & Oberley, 2002). As a result, non-adherence to treatment is common and problematic for HD patients and is associated with a number of psychological factors including depression, illness and treatment perceptions, and self-efficacy (Clark, Farrington & Chilcot, 2014).

1.3.2 Loss, dependency and death

According to the UK Renal Registry 16th Annual Report (UK Renal Association, 2013), the relative risk of death on RRT in 2012 was 6.1 times that of the general population (for all age groups collectively). Enduring conflicts about life and death as well as dealing with uncertainty about the future, loss and dependency are unique issues faced by those undergoing HD treatment. Some of these were emphasised in a qualitative study by Hagren, Pettersen, Severinsson, Lützén & Clyne (2001) who analysed interview transcripts of a group of male and female Swedish dialysis patients, and identified loss of freedom, dependence on the dialysis machine as a lifeline and reliance on caregivers as the main ‘areas of suffering’. In a later study, the same group of researchers conducted interviews to gain a more in depth understanding of how these issues impacted on patients’ lives (Hagren, Pettersen, Severinsson, Lützen, & Clyne, 2005). From analysis, they recognised a number of themes including ‘not finding space for living’, ‘feelings evoked in the care situation’ and ‘attempting to manage restricted life’. The interviewees complained of not being able to live life to its full, not being able to fully participate in society, and feelings of vulnerability and ‘emotional distance’ from caregivers. The authors suggest that the feeling of ‘emotional distance’ could signify an underlying ‘existential struggle’ caused by the fact that the illness acts as a continuous threat to patients’ existence and means patients feel as though they are essentially living on ‘borrowed’ time.

In a similar vein, it is possible that patients may experience a sense of ambivalence towards the dialysis machine itself, as it can represent a life-line as well as a significant burden. Polashek (2003) commented that patients are forced to cope

with the paradox of being dependent on the machine, while remaining independent in the rest of their lives. This issue is often worsened by renal staff and family who put pressure on the individual to lead a 'normal life' between dialysis sessions, since they may show no signs of illness. As well as being a constant reminder that their time is limited, the intrusiveness of the treatment also reminds patients that the situation is beyond their control (Devins et al, 1983). Alexander (1976) labelled this idea as the 'double bind', referring to the fact that patients are forced to balance their gratitude for the technology with their frustration at the imposition it places on their lives. This has more recently been termed the 'compliance-independence tight rope' (Curtin, Oberley & Sacksteder, 1997). Researchers have also suggested that it may be difficult for renal patients to put forward their viewpoint or voice their experiences of suffering, since it is so different from the dominant discourse of professionals, which appears to neglect the chronicity of the condition and accompanying treatment (Faber, 1999).

1.3.3 Social difficulties

The complex HD treatment regime can have an extreme impact on a patient's social world, including family relations and friendships. High levels of sexual and marital dysfunction have been found in dialysis patients, which have been partly attributed to the physical effects of dialysis and partly to social constraints of illness (House, 1987). Patients have also reported strong feelings of guilt about the perceived burden on family life and about spending so much time in clinic, away from family members (Tong et al, 2009).

The time constraints as well as impaired physical ability associated with HD treatment can also affect patient ability to maintain active employment. This can lead to substantial financial struggles, and add to the burden placed on families. Studies have found that dialysis patients aged 18-64 work significantly less compared to the general working age population. For example, a Dutch study found that only 35% of ESRD patients of working age were still employed at the start of dialysis, compared to 61% of the general population (van Manen et al, 2001).

1.3.4 Symptom burden

Studies have shown that patients on dialysis suffer from a high number of symptoms, thought to be comparable to those of patients with cancer and HIV, and that symptom burden strongly correlates with depression (Weisbord et al, 2005). Tiredness, pain and itching appear to be the most important physical symptoms reported (Merkus et al, 1999; Davison & Jhangri, 2010). Pain symptoms can include

those related to renal failure and its treatment (e.g., muscle cramps and fistula pain) as well as non-specific symptoms such as headaches and back pain (Devins et al, 1990). Gamondi et al (2013) asked 123 patients to complete a set of self-report measures of pain, associated symptoms and overall symptom burden at several dialysis units in Switzerland. The results showed patients experience multiple and severe symptoms which interfere with daily living and affirmed that the dialysis treatment itself can actively trigger pain for some individuals.

Other commonplace symptoms which coincide with dialysis include lack of appetite, thirst and nausea (Gamondi et al, 2013). Recent studies have confirmed other frequent symptoms for dialysis patients are insomnia and lack of sleep (Mucsi et al, 2004). Unfortunately, such symptoms are often left un-recognised by renal staff, possibly due to the fact that physicians and staff accept them as part of the ESRD experience (Claxton et al, 2010).

Dialysis patients are also likely to suffer from co-morbidities, which act as either causes or consequences of kidney failure. Long-term survivors of kidney failure are almost certain to experience vascular access problems, bone disease, electrolyte imbalances, cardiac arrhythmia, hyperparathyroidism and one or more failed transplants over the course of their illness (Harris & Brown 1998).

1.4 Depression in Dialysis Patients

Considering the number of psychosocial stressors inflicted on dialysis patients, as well as the unpredictable and pervasive nature of the condition, it is not surprising that psychological distress, including depression and anxiety, is common within this population. However, although psychological distress is frequently referenced in the health care literature, it is seldom defined as a distinct concept (Ridner, 2004). Until recently, research within the nephrology field has mostly focussed on measuring specific psychiatric disorders, such as depression, anger and anxiety, rather than on the broader concept of emotional or psychological distress. Similar to other chronic illnesses, depression is typically considered to be the most important clinical psychiatric problem (Kimmel, 2002) although Cukor et al (2007) suggest anxiety disorders may also be highly prevalent.

1.4.1 Depression: measuring prevalence

Most data on depression in CKD patients is available from in-centre dialysis populations and has been determined by patient self-report questionnaires assessing presence and severity of symptoms (e.g., Cukor, Peterson, Cohen &

Kimmel, 2006; Kimmel, Cukor, Cohen & Peterson, 2007). Such studies have indicated the prevalence of depression in ESRD to be about four times that of the general population. However, a number of issues have been raised regarding these findings, mainly centred on confusion with defining and recognising depression and the lack of well-validated assessment tools. These issues will be discussed in further detail below.

In clinical terms, 'depression' has a specific definition as a psychiatric disorder with established diagnostic criteria. These criteria are outlined within the Diagnostic and Statistical Manual of Mental Disorders – Fourth Edition (DSM-IV; APA, 1994) as low mood or anhedonia (loss of interest or pleasure in everyday activities) present for at least two weeks, accompanied by other somatic, cognitive and behavioural symptoms. These include; loss of energy, over or under-eating, problems with sleep, agitation, difficulty concentrating, feelings of worthlessness, helplessness, excessive guilt and thoughts about death and suicide. Physicians tend to differentiate between different depressive disorders (such as major depression and dysthymic disorder, a milder more chronic type) on the basis of severity, duration and number of symptoms. In contrast, 'depressive symptoms' can include feelings of sadness accompanied by altered mood, somatic symptoms and loss of pleasure in activities, but not to a sufficient level of severity to warrant a clinical diagnosis. In reference to dialysis patients, researchers often fail to clarify the clinical distinction between different depressive disorders and depressive symptoms, which can lead to uncertainty regarding prevalence estimates (Cukor et al, 2006).

The clinical diagnosis of depression requires trained professionals to conduct a diagnostic assessment. This is typically via a structured or semi-structured interview which can be costly and time-consuming. Therefore, when conducting depression screening with chronic illness patients, clinicians tend to rely on standardised self-report measures which require patients to rate symptom severity or frequency. These are easier and quicker to administer. However, this creates difficulties since many of the somatic symptoms pinpointed by these measures overlap with symptoms of kidney failure (or uraemia), including loss of appetite, sleep disruption, fatigue and cognitive dysfunction (Cukor et al, 2007). These measures therefore lack specificity and tend to overestimate the prevalence of depression (Palmer et al, 2013).

The Beck Depression Inventory (BDI) and the Patient Health Questionnaire (PHQ) are two measures frequently used to screen for depression in this population

(Watnick, Wang, Demadura & Ganzini, 2005). The BDI is a 21-item questionnaire which has been validated in chronic dialysis patients and is therefore considered a reliable instrument (Hedayati, Bosworth, Kuchibhatla, Kimmel, & Szczech 2006). However, it has been criticized for being too extensive to be used as an effective repeated measure (van den Beukel et al, 2012). In order to manage the issue of criterion contamination, the Cognitive Depression Index (CDI) was developed as a subscale of the BDI which excludes somatic items. Sacks, Peterson & Kimmel (1990) have suggested this may be a more valid measure to use with ESRD patients. However, other researchers claim that the cognitive and somatic elements of depression cannot be easily separated. For example, Chilcot, Wellstead and Farrington (2008) screened HD patients with both measures and found that the BDI had a greater sensitivity and specificity when compared to a diagnostic interview, than the CDI.

More recently, van den Beukel et al (2012) compared results obtained with the 5-item Mental Health Inventory (MHI) (subscale) of the 36-item Short-Form Health Survey Questionnaire to scores obtained with the BDI. Their results suggest that the MHI may be an appropriate screening tool for depression among dialysis patients. This measure was originally designed to assess anxiety, depression, loss of behavioural or emotional control and psychological well-being (Ware, 1995). Since many dialysis patients present with a multitude of problems in addition to established depressive symptoms, the authors argue that this measure might be more suited to identifying the spectrum of depressive conditions common in this population. Novak, Mucsi & Mendelssohn (2013) discuss the application of this more holistic approach within the context of recent pressures to focus on patient-reported outcomes (PRO). However, the question of which measure is the most appropriate for depression screening in dialysis patients remains subject to debate.

Problems with variations in the definition of ‘depression’ and the lack of disease specific-validated assessment tools has therefore meant that establishing a definitive prevalence of depressive symptoms in dialysis patients has been challenging. The Dialysis Outcomes and Practice Patterns Study (DOPPS; Lopes et al, 2004) was a multicentre international observational study of dialysis outcomes which showed that, although the rate of physician-diagnosed depression varied considerably between countries (from 2% in Japan to 21.7% in USA), there was no significant difference in the rates of self-reported depressive symptoms (using the Centre for Epidemiologic Studies Depression Scale; CES-D). The authors concluded that the variation in physician ratings was due to a difference in cultural

beliefs. In addition, lower rates of depression are reported when symptoms are defined according to the DSM-IV (e.g., Soykan et al, 2004), whereas higher rates are reported when mild-moderate depressive symptoms are included using self-report measures like the BDI (e.g., Kimmel, Thamer, Richard & Ray, 1998).

A recent meta-analysis of studies of depression in adults with CKD (Palmer et al, 2013) concluded that approximately 25% of adults with CKD have interview-based depression. This supports recent study findings that have estimated a prevalence of between 20-30% (Wilson et al, 2006; Martin, Tweed, & Metcalfe, 2004). Despite the debate surrounding prevalence, most researchers agree that it is the most important psychiatric problem (Kimmel, Weihs & Peterson, 1993). Some studies have proposed that prevalence is higher following the start of dialysis (Watnick, Kirwin, Mahnensmith & Conato, 2003), although this could be due to the confounding presence of other psychiatric disorders at this stage, such as adjustment disorder (Chilcot et al, 2011a). Studies looking at the relationship between extra-renal co-morbidity and depression have shown contradictory findings, with some reporting an independent relationship (e.g., Chilcot et al, 2011a) and others reporting that increasing levels of co-morbidity increase depression (Boulware et al, 2006). The previously discussed issues with measuring depression, as well as problems measuring co-morbidity, could account for the mixed findings.

1.4.2 Depression: effect on outcomes

Depression has been associated with a number of clinically significant outcomes within the dialysis population. Amongst the most frequently studied outcomes are QOL and mortality. Research concerning the main effects of depression on these outcomes will be outlined below.

With the increased survival of dialysis patients over the past decade, increased attention has been dedicated to QOL as an outcome of interest. There is some disagreement within the literature regarding an operational definition, however, the World Health Organisation (1995) defines it as “an individual’s perception of their position in life in the context of culture and value systems in which they live and in relation to their goals and expectations, standards and concerns” (p. 1405). They also point out that it is a broad-ranging concept which can be affected by a person’s physical health, psychological health, level of independence and relationship to features of their environment. The most widely studied aspect of QOL in the context of chronic illness is ‘Health Related Quality of Life’ (HRQOL). This construct provides information about a patient’s perception of the physical and psychosocial

impact of the illness and treatment on their lives. Both clinically diagnosed depression and the presence of depressive symptoms have been found to be associated with impaired HRQOL in dialysis patients (Finkelstein, Wuerth & Finkelstein, 2010). Furthermore, the Spanish Cooperative Renal Patients Quality of Life Study Group (Vasquez et al, 2003) found that anxiety and depressive symptoms were the most important predictors of HRQOL. Also, in a longitudinal study, high psychological distress was found to be associated with diminished QOL in dialysis patients over time (Franke, Reimer, Philipp & Heemann 2003). Overall, it is clear that psychological distress (including anxiety and depressive affect) has a significant impact on HRQOL. As a result, measures of depressive affect are often included as items and scales in QOL indices (Kimmel, 2001).

The relationship between depression and mortality in CKD patients is a complex one. Early studies using a variety of self-report questionnaires to allow a cross-sectional assessment of depressive symptoms were able to verify an association (e.g., Peterson et al, 1991). However, they were limited by small sample sizes and poor designs. In contrast, later studies with more robust designs failed to demonstrate any association (e.g., Kimmel et al, 1998). However, in a recent longitudinal study, Kimmel et al (2000) monitored depressive symptoms over a period of up to 5 years in chronic dialysis patients, which revealed some interesting results. They found that, although depressive affect did not predict mortality, time-variant changes of depressive affect were strong predictors of survival over time. In other words, acute changes in mood were related to lower survival rate. Also Hedayati et al (2008) found that dialysis patients were twice as likely to die or require hospitalisation within a year compared to those without depression. Interestingly, their data showed that physician diagnosed clinical depression was a better predictor of mortality than self-reported depressive symptoms. The same group of researchers ran a prospective observational cohort study of stage 2-5 CKD pre-dialysis patients and found that a diagnosis of major depressive episode at baseline was associated with an increased risk of a composite death, hospitalisation or progression to dialysis, independent of co-morbidities and disease severity (Hedayati et al, 2010). Adding to this, Drayer et al (2006) showed that depression was able to predict mortality after controlling for a number of demographic and clinical covariates.

1.4.3 Depression: what mediates the relationship with outcomes?

The mechanisms linking depression with poor outcomes in HD patients are not fully understood (Lopes et al, 2002). However, many researchers have proposed a

distinction between a biological and behavioural pathway (Khalil, Lennie & Frazier, 2010).

1) Biological pathway

The biological pathway involves an impact on immune function leading to an inflammatory response. It is thought that ESRD has an underlying inflammatory component that may place sufferers at a higher risk of developing depressive symptoms (Raison & Miller 2001). For example, there is evidence of a link between depressive symptoms and pro-inflammatory cytokine levels. Cytokines are a broad category of small proteins, important in cell signalling. If they are pro-inflammatory, this means they promote systemic inflammation, which can function to make a disease worse by producing fever and tissue destruction. During HD, these cytokines are produced and can enter the central nervous system (CNS) (Khalil et al, 2010). Evidence from animal studies suggests that when pro-inflammatory mediators are present in the CNS, behaviour consistent with depressive symptoms, such as decreased activity, weight loss and impaired learning, is observed (e.g., Wu & Lin, 2008). In addition, depressive symptoms have been hypothesised to stimulate cytokine production in people with chronic illness (Anisman, Merali & Hayley, 2008). Of further relevance, an association has been found between depressive symptoms and elevated levels of C-reactive protein (a marker of inflammation) in HD patients (Dogan, Erkoc, Eryonucu, Sayarlioglu & Agargun 2005). However, researchers are yet to establish whether elevations in the cytokines lead to development of depressive symptoms or vice versa.

Another possible mediating factor is malnutrition. It is well known that chronic HD patients with malnutrition, partly indicated by hypoalbuminemia (abnormally low levels of protein), have an increased mortality rate (Lopes et al, 2002). Additionally, depression is commonly associated with poor adherence to fluid intake, which can heighten malnutrition. A correlation between severity of depressive symptoms and degree of malnutrition has been presented (Koo et al, 2003). However, Kimmel et al (1998) failed to detect an association between the two factors in a group of African-American patients.

2) Behavioural pathway

Another way of understanding the relationship between depression and outcomes is though the behavioural mechanism of adherence. As already discussed, although HD is a life sustaining treatment, it does not completely replace renal function. This

means patients have to engage in permanent lifestyle changes including dietary and fluid restrictions and a complex medication regime. Researchers know that lack of adherence to this regime increases risk of complications (Durose, Holdswroth, Watson & Przygrodzka, 2004) whereas strict adherence can result in a lower mortality risk (Kimmel et al, 1998).

Few studies have examined the relationship between depressive symptoms and dietary adherence in HD patients. Taskapan et al (2005) found that HD patients with depressive disorders were less likely to adhere to fluid restriction and nutritional requirements than those without. Similarly Akman et al (2007) demonstrated dietary non adherence was twice as likely in ESRD patients with depression as those who were not depressed. Conversely, no association was found between depressive symptoms and adherence in a group of Chinese patients receiving haemodialysis (Pang, Ip & Chang, 2001). These findings were potentially limited by the study's reliance on weight gain as a measure of adherence.

It has been proposed that depressive symptoms could influence adherence to medication via the creation of distorted beliefs and thoughts about a lack of perceived benefit from medication (Khalil et al, 2013). Furthermore, depressive symptoms encompass negative impacts on motivation, memory, cognition and attention which may impact a patient's sensitivity to the unpleasant side effects of medication (Wang et al, 2002). This relationship has been demonstrated in many chronic disease populations. For example, Wang and colleagues (2002) reported that severity of depressive symptoms was significantly associated with a decrease in medication adherence in patients with hypertension. However, there is no study to date which has showed this relationship for ESRD patients.

In summary, despite a number of issues with measurement, the weight of evidence means we can be confident in stating that a relationship exists between depression and a number of health-related outcomes, including mortality. However, the exact nature of this relationship remains unclear. It is possible that the relationship is bi-directional meaning depression leads to poorer health and vice versa, or depression could be independently associated with mortality. The pathways described above remain speculative due to mixed findings.

1.5 Illness Perceptions

In recent years, researchers have continued to focus on the relationship between depression and health-related outcomes with the ultimate goal of identifying factors that are amenable to intervention and therefore could lead to favourable consequences for the dialysis patient, their social situation and the service provider (Hale, Treharne & Kitas, 2007). However, there has been slight shift in behavioural research away from compliance and depression, towards more modern concepts of illness beliefs, treatment beliefs and self-management (Kaptein et al, 2010). For example, studies in HD patients have documented an association between a number of different cognitive factors and self-management, including self-efficacy (Brady, Tucker, Alfino, Tarrant & Finlayson, 1997), locus of control, and general health-beliefs (Kutner, Zhang, McClellan & Cole, 2002). This development supports a move away from paternalistic approaches towards increasing 'adherence', to one which helps to empower patients and encourages shared decision making (Bodenheimer, Lorig, Holman & Grumbach, 2002)

One way researchers have conceptualised the relationship between such cognitive factors and outcomes is using illness perceptions, a core component of Leventhal's 'Common-Sense Model of self-regulation' (CSM) (Leventhal & Camerson, 1987; Leventhal, Leventhal & Contrada, 1998). This model has been used extensively within research on chronic illness in order to understand the process of patients' emotional adjustment and coping, following diagnosis.

1.5.1 Common Sense Model of self-regulation (CSM)

The CSM is an adapted version of several social cognitive or problem-solving models, and bares a strong resemblance to the transactional model of stress and coping (Lazarus & Folkman, 1984). Leventhal and his colleagues (1997) originally developed the CSM after studying the factors which influence health promoting behaviours. After discovering that different types of information were needed to influence both attitudes and actions to a perceived threat to health, they wanted to understand what types of adaptations and coping efforts might be required for those experiencing chronic illness. In essence, the model proposes that when an individual is diagnosed with a chronic illness, they construct an organised pattern of beliefs or personal mental model of their condition, in order to make sense of their symptoms. These mental models are known as 'illness representations' and are based on available concrete and abstract sources of information. These representations evolve over time as the individual gains new information and can

function to determine how they respond (Leventhal, Meyer & Nerenz, 1980). Evidence suggests illness representations, or perceptions, consist of the following five components (Petrie & Weinman, 2006):

1) Identity. This is the label or name given to the condition and the symptoms that seem to coincide with it.
2) Cause. These are the ideas an individual holds about the perceived cause or causes of the illness, which may not be bio-medically accurate. These beliefs are based on information gathered from personal experiences, as well as from the opinions and discourses of significant others.
3) Time-line. This is a predictive belief about the likely duration of the illness, for example whether it is acute or chronic. These beliefs can be re-evaluated as time progresses.
4) Consequences. This is what the individual understands the consequences of the condition will be and how it will impact on them physically and socially.
5) Curability/controllability. This is an individual's beliefs about whether the condition can be cured or controlled, and the degree to which they play a part in achieving this control.

This set of dimensions is thought to be interrelated, functioning as group of beliefs or schema, rather than as single cognitions (Leventhal, 1998). The figure below is a diagrammatic representation of how this dynamic, self-regulatory system works.

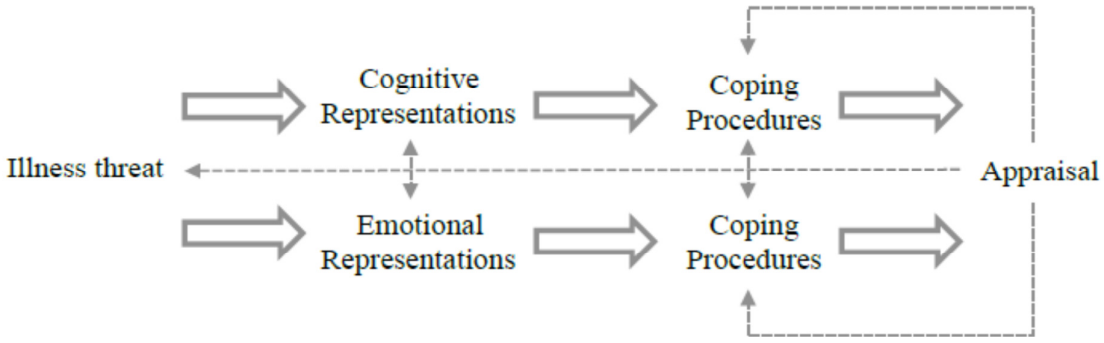

Figure 1. Diagram representing the Common Sense Model of Self-Regulation (Leventhal et al, 1997)

As the diagram shows, the model postulates two different parallel pathways for processing a health threat, which continuously interact as the individual adapts to illness. The first pathway comprises a cognitive representation (which encompasses the five components outlined above) and related coping strategies (e.g., "what is it and what can I do about it objectively?"). The second pathway comprises an

emotional representation and related coping strategies (e.g., "how do I feel about it?"). Feedback loops allow for appraisal of the effectiveness of the coping strategies, which influences the cognitive and emotional representations, which then influences future coping. This process of continuous appraisal and re-appraisal is believed to reflect a common-sense 'IF-THEN' judgement which directly leads to coping or self-care behaviour. 'IF' is interpretation of illness and 'THEN' refers to the procedure adopted in response to threat. For example, a patient may hold the belief that 'IF my treatment does little to control my disease, THEN undertaking the required facets of self-care may not be necessary' (Leventhal et al, 1998).

A meta-analytic review confirmed the *a priori* hypotheses of this model (Hagger & Orbell, 2003). It declared that negative cognitive representations (beliefs in serious consequences, a strong illness identity and a chronic timeline) were negatively related to adaptive illness outcomes (psychological well-being, social and role functioning and vitality), but positively related to the maladaptive illness outcome of psychological distress. High perceived control was also positively correlated with psychological well-being and vitality. The model posits that coping behaviour mediates the relationship between illness representations and outcomes, however, this review indicated only low-moderate correlations between the illness perception dimensions and coping behaviour. The authors argue this could be due to the measures of coping behaviours lacking specificity or the possibility that coping behaviours act as moderators by either exacerbating or hindering the influence of illness representation on outcomes. Therefore, the precise position of 'coping behaviours' as a mediating mechanism in this model, remains open to speculation.

1.5.2 Illness perceptions in HD patients

Several qualitative studies have investigated general illness perceptions for ESRD patients. Some have shown that HD is commonly perceived as an extremely demanding and burdensome treatment which disrupts work, family and social aspects of life. (e.g., Krespi, Bone, Ahman, Worthington & Salmon, 2004). Others have commented on the constant emotional and psychological adjustments to changing health states which can severely disrupt a patients' integration of a positive sense of self into their social worlds (e.g., Gregory, Way, Hutchinson, Barrett, & Parfrey, 1998). A quantitative study by Griva, Jaysena, Davenport, Harrison & Newman (2009) measured illness perceptions across different treatment modalities of RRT. The research group found that dialysis patients reported significantly more symptoms, held lower control beliefs, and perceived more illness and treatment disruptiveness, than transplant patients. These findings echo those of

earlier studies which show that when treatment is perceived as less intrusive, overall illness and treatment perceptions are more positive (Devins et al, 1990).

1.5.3 Illness perceptions and outcomes

The five components of illness representations have been operationalised in the Illness Perception Questionnaire (IPQ), which also measures treatment perceptions (Weinman, Petrie, Moss-Morris & Home, 1996). This has been used to investigate the utility of the CSM model in understanding the role of illness perceptions in several varieties of chronic illness. A collection of studies have specifically focussed on how illness perceptions impact on physical and psychological health outcomes in ESRD patients.

O'Connor, Jardine & Millar (2008) applied the CSM to the prediction of self-care behaviour in HD patients, in conjunction with the process model of coping (Lazarus & Folkman, 1984). Lazarus and Folkman's model of coping suggests that patients may use two possible types of coping; problem-focussed or emotion-focussed, in order to alleviate psychological distress. O'Conner et al (2008) decided to integrate the two models, since previous research suggests that adherence to dietary and fluid restrictions and medication regimes may be enhanced through the adoption of problem-focussed coping strategies and that maladaptive coping strategies may be less helpful and associated with poor adherence (Penley, Tomaka & Weibe, 2002). The researchers found that illness perceptions predicted self-care behaviours over and above clinical and medical factors. Furthermore, scores indicating the use of emotional illness representations were better able to predict medication and dietary adherence than general psychological distress, highlighting the importance of measuring illness-specific distress when screening for psychological problems. Also, emotion-focussed coping was more closely associated with variation in adherence to fluid restriction, perhaps indicating that the use of emotion-focussed coping skills (such as positive-reframing) allows individuals to disregard or forget fluid restrictions and are less helpful for encouraging adherence to self-care behaviour. Finally, the importance of timeline beliefs were highlighted since those who believed their disease was temporary, were less likely to adhere to the dietary guidelines and vice versa. The importance of timeline beliefs was also highlighted by Chilcot, Wellsted & Farrington (2010), who compared differences in illness perceptions between fluid adherent and non-adherent HD patients. Their results indicated non-adherent patients held significantly lower timeline perceptions as compared to adherent patients, implying that ESRD patients who do not perceive

that their illness is chronic, are less likely to adhere to recommended fluid restrictions.

Two studies have examined how illness perceptions are associated with survival in dialysis patients. Van Dijk et al (2009) found that treatment control beliefs play a major role. Patients who perceived their treatment to be less effective suffered from a higher level of mortality, after adjusting for clinical and socio demographic variables. An additional study by Chilcot, Wellsted, Davenport and Farrington (2011b) added weight to this claim by demonstrating that perceptions pertaining to treatment control predicted survival. Collectively, these results provide support for the theory that low perceived treatment control leads to maladaptive health-care behaviour such as non-adherence, which can in turn increase mortality.

Illness perceptions have also been found to be important determinant of QOL in this population. After controlling for confounding variables, Timmers et al (2008) found that illness perceptions significantly contributed to aspects of QOL. More specifically, the results showed that a strong illness identity, many perceived negative consequences and low personal control were associated with lower well-being. These findings endorse those of earlier studies that illustrate stronger emotional representations are associated with worse outcomes (O'Conner et al, 2008). In a longitudinal study, Covic, Seika, Mardare and Gusbeth-Tatomir (2006) followed up patients after two years of treatment and concluded that a lower emotional response meant better physical scores. These researchers also found that illness perceptions improved over time. After the two years, patients had less negative emotional perceptions, a better understanding of their illness and a better perception of control. Illness perceptions can also predict depressed mood. Treatment disruptiveness was found to be a powerful predictor of levels of depressed mood in a group of ESRD patients (Griva, Davenport, Harrison & Newman, 2010) and Chilcot et al (2011b) found illness consequences, coherence and personal control independently predicted depression in a sample of HD patients.

Taken together, findings from research on illness perceptions in the ESRD population indicate that they are an important determinant of health-related outcomes including treatment adherence, survival and QOL. Some researchers have even suggested they may be more powerful predictors of outcome than clinical factors (Chilcot et al, 2011b).

1.6 Interventions

Since clinicians have been made aware of the important impact psychological distress and maladaptive illness perceptions can have on health-related outcomes in dialysis patients, increased emphasis has been placed on designing suitable methods to help ameliorate distress symptoms and improve maladaptive illness perceptions. The limited pool of research so far has mainly focussed on pharmacological and psychotherapeutic interventions.

1.6.1 Pharmacological interventions

Considering the amount of research to date indicating the existence of a significant link between depression and poor outcomes for dialysis patients, only a scarce number of studies have examined the pharmacological treatment of depression in this population. Most of the trials published have been limited by small sample sizes and other methodological problems. With regards to PD patients, a non-randomized observational study of anti-depressant medication reported some improvement in depressive symptoms (Wuerth, Finkelstein & Finkelstein, 2005). Another study by Atalay et al (2010) reported that treatment with selective serotonin reuptake inhibitors (SSRIs) was associated with a decrease in depressive symptoms in chronic PD patients. However, these findings were limited by a lack of control group and the fact that the average BDI score remained above the cut-off for depression at the end of treatment. With regards to HD patients, a study by Koo et al (2005) found that a group of depressed dialysis patients treated with an SSRI alongside psychotherapy had statistically lower depression scores at the end of treatment. However, again the findings were limited by a lack of placebo-control group and a short-term follow-up. Finally, a randomised controlled trial of treatment using fluoxetine in 14 chronic HD patients with major depression lead to a statistically significant improvement in depression after 4 weeks, although this improvement was not sustained at 8 week follow-up (Blumenfield et al, 1997).

The exclusion of ESRD patients from large antidepressant trials has been largely due to concerns regarding the possibility of adverse events and the lack of data about the safety of using antidepressants with this patient group (Glassman et al, 2002). Hedayati, Yalamachilli, & Finkelstein (2012) point out that many antidepressants are highly protein bound and not removed sufficiently by the dialysis procedure, which could cause a build-up of potentially toxic metabolites in the blood. There is also a risk of multiple drug interactions since dialysis patients frequently suffer from co-morbidities and are therefore prescribed numerous

medications. Furthermore, it is widely recognised that many antidepressants can have noticeable side effects and the possibility of cardiac side effects could be a particular problem for ESRD sufferers. Reviews of the literature to date have concluded that more trials are needed to establish the effectiveness of SSRIs, as well as research their side effects and possible drug-drug interaction (Hedayati et al, 2012).

1.6.2 Psychological interventions

The treatment of psychological conditions in dialysis patients has received little attention, particularly with respect to psychological interventions. This means there is currently little evidence concerning the most effective treatment options for dialysis patients with co-morbid depression. A recent review by Sharp, Wild & Gumley (2005) found most psychological interventions aiming to improve fluid adherence in dialysis patients tend to use strategies and techniques from behavioural models, for example token economies (Carton & Schweitzer, 1996), self-regulation/self-monitoring (Christensen, Moran, Weibe, Ehlers & Lawton, 2002), social reinforcement (Mosley, Eisen, Bruce, Brantley & Cocke, 1993), skills training (Molaison & Yadrick, 2003), stress management (Tsay, 2003) and the adoption of functionally equivalent behaviours (Vipond, 1991). Other studies are multifaceted, using elements of cognitive or behavioural therapy, and many are supplemented with patient education. The authors of this review highlight some limitations of the research to date which include small samples, poor quality and lack of statistical power. In addition, many of the studies do not consider how the intervention impacts on psychosocial outcomes. However, they conclude that, overall, psychological interventions appear to have some clinical benefit and highlight the recent shift towards interventions utilising a more integrative approach, which have shown promise.

It is thought that behavioural strategies alone are able to achieve good outcomes with dialysis patients in the short-term, but that cognitive behavioural therapy (CBT) has more potential to achieve long-term behaviour change (Kutner, 2001). CBT is a structured, short-term and goal-driven therapy which integrates both the principles of cognitive theory and behavioural techniques. Cognitive theory dictates that our emotions are driven by cognitive distortions, in other words, the misinterpretation of situations or events. CBT therefore aims to teach patients effective ways of managing low mood through the use of coping strategies such as thought challenging, problem-solving and adjustment of their behaviour. CBT is well-

recognised as a viable treatment option for a number of psychiatric disorders in variety of populations (Beck, 2005).

Since the 1990s, there has been a small but growing collection of evidence that supports the effectiveness of CBT with ESRD sufferers. Hener, Matisyohu & Har-Even (1996) reported a group of patients who had supportive therapy or CBT maintained better emotional, interpersonal, behavioural and cognitive adjustment to PD than those in the non-treatment group. Cukor (2007) adapted CBT treatment so it could be administered 'chair side' at the dialysis unit. This was conducted for individual patients with major depression, and resulted in a significant decrease in BDI scores at the end of treatment. In addition, a recent trial of CBT with 84 HD patients with major depression was conducted in Brazil (Duarte, Miyazaki, Blay & Sesso, 2009). Patients were randomized into a control group (receiving standard care) or an intervention group who received 12 weekly group CBT sessions, followed by monthly maintenance sessions. Results showed a significant decrease in depression scores in the CBT group compared to the control group, which was confirmed with standardised interviews, and maintained 6 months after the intervention period. The group receiving CBT also showed significant improvements in some QOL dimensions (burden of kidney disease, cognitive function, quality of social interaction, sleep and overall health). The broader benefits of CBT have also been observed in a study of 69 ESRD patients in Louisiana after hurricane-related trauma (Weine, Kutner, Bowles & Johnstone, 2010). For this study, social workers were trained using kits supplied by the National Kidney Foundation, which applied a cognitive-behavioural framework. Those patients who discussed this material with their social workers achieved a significant amelioration of depressive symptoms compared to those who chose not to. Overall, these findings suggest how, with focussed training, CBT can be applied for more widespread use in this setting.

Studies focussing on interventions designed specifically to alter illness perceptions in chronic illness populations have shown that inaccurate perceptions are amenable to change and that this can have a positive effect on health-related outcomes. For example, Petrie, Cameron, Ellis, Buick & Weinman (2002) designed a brief psychological hospital-based intervention to change inaccurate and negative illness perceptions of myocardial infarction (MI). The intervention consisted of the same broad framework, but specific content was adapted according to each individual's illness beliefs. Sessions included education about the pathophysiology of MI, identifying and challenging extreme or negative illness beliefs and development and review of a recovery action plan. Results indicated that the intervention was

successful in changing patient's perceptions of their MI, speed of return to work at 3 months and lower reported rates of angina symptoms. Another study by Petrie, Perry, Broadbent & Weinman (2012) used text messages targeted to individual asthma patients' individual illness and treatment beliefs which positively modified beliefs and increased adherence rates by 10%.

So far, very few studies have applied similar approaches with ESRD patients. Karamanidou, Clatworthy, Weinman, Horne et al (2008) demonstrated the feasibility of using an intervention addressing treatment perceptions and improving patients' understanding and perceived efficacy of phosphate –binding medications. Jansen, Heijmans, Rijken & Kaptein (2011) also designed a behavioural self-regulation intervention with the aim of generating 'positive but realistic' beliefs about disease, treatment and changing maladaptive beliefs, for a group of dialysis patients. They also wished to increase self-efficacy and stimulate behaviour that supported autonomy in patients and their partners. The intervention used a similar structure to that of Petrie et al (2002), and was successful in implementing an integrated approach in this setting. However, the study sample was small and the outcome was focussed on employment rather than health-related benefits.

In summary, evidence for interventions focussing on reducing depression in dialysis patients has been mixed. There are some supportive findings for the use of anti-depressants, although a number of issues remain unresolved. A few behavioural interventions have been applied, but only looking at the impact on behavioural change, and not on mood. With regards to CBT, although many existing studies suffer from small sample sizes and inadequate methodology, the results so far are encouraging. A couple of studies have also examined the feasibility and efficacy of using interventions designed to change maladaptive illness perceptions. In general, there seems to be a lack of research on the effectiveness of psychological interventions aimed at improving symptoms of psychological distress in HD patients and the impact of such interventions on physical health outcomes remains unknown. Little is known about which illness perceptions are associated with psychological distress or depression in dialysis patients and there is a need and for more trials of interventions designed to alleviate distress.

1.7 Expressive Writing (EW)

1.7.1 Development of EW procedure

Over the past 30 years, a large base of experimental findings has accumulated to demonstrate the clinically meaningful changes brought about through the process of EW, or emotional expression (Smyth & Pennebaker, 2008; Frattaroli, 2006). This model emerged from the core principle of psychotherapy; that the disclosure of emotional experiences is beneficial for clients. Pennebaker et al (1985, 1989) were the first to scientifically validate this process. They examined the consequences of the technique by manipulation using an experimental design. In their pioneering study, Pennebaker and Beall (1986) randomly assigned participants to write either about traumatic events or neutral topics, for several consecutive days. They compared the outcomes of four different writing groups: a trauma-fact group, a trauma-emotion group, a trauma-combo group and a control group. The surprising results revealed that, several weeks after writing, the trauma-combo group (who wrote about both the facts and emotions surrounding their trauma) exhibited a significant reduction in illness-related visits to their doctor, as compared to the other three groups. In a series of subsequent experiments, this group of researchers were able to show that, in order to obtain positive health effects, the writing instructions had to focus participants on the emotional evaluation of their experience, beyond a factual description of events (Pennebaker & Beall, 1986; Pennebaker, Colder & Sharp, 1990; Pennebaker & Francis, 1996). The idea that disclosing thoughts and feelings concerning a traumatic event can lead to objectively measurable health improvements was unique, and triggered a long tradition of research investigating the effects elicited by the EW paradigm.

Early studies, mainly conducted with health college students, established the basic writing EW template to be replicated and adapted over time. The typical set-up involves asking participants to write about their deepest thoughts and feelings regarding an individually selected upsetting experience or a predetermined stressful situation for 15-20 minutes over 3 to 4 brief writing sessions. This is usually compared with a group instructed to write about unemotional neutral topics. After a decade of research using university students, the exciting findings inspired researchers to begin examining EW effects with a more varied sample. This mostly included people in the community who were currently experiencing or had previously experienced an upsetting event. These studies revealed interesting additional benefits, from increased speed of re-employment (Spera, Buhrfeind &

Pennebaker, 1994) to helping male offenders to take fewer hospital trips (Richards, Beall, Segal & Pennebaker, 2000). Since then, clinicians have been keen to adapt this low cost and accessible technique for use with those suffering from specific health risks and diagnosed health conditions. To allow this, researchers have started to vary the experimental diameters (including number and duration of sessions, instructions and time of follow-up assessment) (Mogk, Otte, Reinhold-Hurley & Kroner-Herwig, 2006).

EW generally has an immediate short-term negative cost (i.e., increase in distress, negative mood and physical symptoms), although this does not appear to be detrimental or pose a longer-term risk to participants (Hockemeyer et al, 1999). However, at long-term follow-up, studies continue to find evidence of benefits for both objective and subjective physical health and subjective emotional health outcomes (Baikie & Wilhelm, 2005). In a meta-analysis of 13 studies of EW with physically and psychologically healthy individuals, Smyth (1998) found a moderate effect on outcome (d=0.47), representing a 23% improvement in overall health. Frisina, Borod and Lapore (2004) conducted a meta-analysis of EW in clinical populations and found a significant effect on outcome (d=0.19). They concluded that EW can be beneficial but differentially effective for an array of physical and psychological outcomes. The most recent and comprehensive meta-analysis by Frattaroli (2006) indicated an overall more modest effect size of around d=0.15. However, Smyth & Pennebaker (2008) argue that for such a brief intervention to have an effect on meaningful outcomes, several weeks afterwards, deserves admiration. There is not scope to discuss the entirety of such findings to date in this paper but the main results regarding the effects of EW on physical and psychological outcomes, relevant to its application within a clinical health setting, will be summarised.

1.7.2 EW: effect on physiological outcomes

In early studies, some of the most striking benefits of EW were improvements to biological measures of immune functioning. T-helper cells and CD4 are types of white blood cells which help to protect the body from infection, and can therefore act as measures of immune system strength. EW was shown to enhance activity of T-helper cells in students (Pennebaker, Kiecolt-Glaser & Glaser, 1988) and significantly increase CD4+ lymphocyte counts in HIV patients (Petrie, Fontanilla, Thomas, Booth & Pennebaker, 2004). Another study focussed on the immune response to the Epstein-Barr virus (a virus which most adults carry and which can be reactivated by stressful events) (Esterling, Antoni, Fletcher, Margulies &

Schneiderman, 1994). This found that participants assigned to express emotions about stressful events verbally or through writing had reduced amounts of antibodies against the EBV virus. Finally, a study by Petrie, Booth, Pennebaker, Davison and Thomas (1995), demonstrated improved responses to hepatitis B vaccination in medical students who engaged in EW.

A number of studies have looked into the effects of EW on other wider parameters of immune functioning. For example, clinical trials have shown improved lung function in patients with asthma at 4-month follow-up (Smyth, Stone, Herwitz & Kaell, 1999). There have also been benefits for patients with rheumatoid arthritis, with results indicating improvements in physical functioning (Kelley, Lumley & Leison, 1997) and reduction of disease severity (Smyth et al, 1999). In addition, Wilmott, Harris, Gellaitry, Cooper & Horner (2011) assessed the effects of written disclosure on health care utilization and clinical outcomes in patients who had experienced their first MI. The writing procedure was associated with fewer GP and hospital visits, less prescribed medication, lower blood pressure and fewer reported cardiac symptoms relative to controls. The long-term effects of EW on blood pressure has also been shown by McGuire, Greenberg and Gerwitz (2005) who found those who participated in the emotional disclosure exhibited lower systolic and diastolic blood pressure one month after writing. The effects of lowered health care utilisation are of particular interest due to their implication for health care cost, and have been investigated by a number of other researchers who have shown found similar results for frequent health clinic attenders (Gidron, Peri, Connelly & Shalev, 1996) for patients following a minor surgical operation (Solano, Donatti, Pecci, Persichetti & Colaci, 2003), and for children with Cystic Fibrosis (Taylor, Wallander, Anderson, Beasley & Brown, 2003).

The benefits of EW have also extended to overall symptom reduction; with Broderick, Junghaenel and Chwartz (2005) demonstrating reduced pain and fatigue in fibromyalgia patients and Norman, Lumley, Dooley and Diamond (2004) finding lower rates of evaluative pain among women with chronic pelvic pain. Finally, a number of studies have applied the writing paradigm to cancer patients with positive results. In a randomised controlled trial, Stanton, Danoff-Bur, Sworowski, Collins and Branstetter (2002) showed that women with breast cancer who were asked to express their deepest thoughts and feelings regarding their experience of illness, reported significantly fewer negative symptoms and had fewer cancer-related medical appointments than the control group at follow-up.

1.7.3 EW: effect on psychological outcomes

As well as the beneficial impact this intervention can have on physical health markers, there is substantial evidence that EW can positively affect aspects of psychological health. To begin with, all participants in many of the previously cited studies consistently reported that writing about emotionally rousing experiences was a valuable and meaningful experience. Pennebaker (1989) also remarked on the praise given by participants at long-term follow-ups, many of whom commented that the process allowed them to think differently about their trauma.

More substantiated improvements in psychological health have also been evidenced. Studies have shown better subjective mental well-being for patients following their first MI who take part in EW (Willmott et al, 2011). More recently, Craft et al (2012) found that early breast cancer survivors who wrote about the trauma of their breast cancer or facts about their breast cancer showed greater improvement in their QOL compared to those who did not write or to those who wrote about a self-selected traumatic event. Another study focussing on breast cancer, instructed participants to focus on their experience of the illness and guided them to write four focussed essays on emotional disclosure, cognitive appraisal, benefit finding and looking to the future, on four consecutive days (Gellaitry, Peter, Bloomfield & Horner, 2010). At six month follow-up, the EW group had higher ratings of perceived emotional support which was associated with lower rates of depression and anger, and higher rates of social and family well-being. Broderick et al (2005) found that EW led to enhanced overall psychological well-being in fibromyalgia sufferers. This was measured using a QOL measure, the State-Trait Anxiety Scale (STAI-S) which assesses anxiety symptoms and the Beck Depression Inventory II (BDI) which assesses symptoms of depressed mood. Finally, Averill, Kasarskis and Segerstrom, (2013) have shown that patients with amytrophic lateral sclerosis (a fatal neuromuscular disease) reported high levels of psychological well-being three months after writing, but not at six months. They also found that those who were particularly ambivalent about expressing emotion were the most likely to benefit from the EW task. However, overall, statistical reviews of these findings have asserted that EW effects for psychological health do not appear to be as robust or consistent as those for physical health (Frisina et al, 2004).

1.7.4 EW: theoretical development

"Two strong conclusions can be made with regard to the benefits of expressive writing. First expressive writing has health benefits. Second, no one really knows why."

King (2002, p119)

A range of theories have been proposed to explain the effects of the EW procedure (Pennebaker & Chung, 2007). Early researchers argued the effects of the writing task were linked to the Freudian concept of catharsis (1904). This theory proposes that, following a disturbing or traumatic event, the memory of said event may be suppressed, whilst the emotion of the associated affect continues to exist in one's consciousness in the form of anxiety. Therefore, describing such an event in detail can have a cathartic effect by revealing the suppressed memory, releasing the associated affect. In support of this, Breuer and Freud (1966) recognised that 'hysterical' symptoms were likely to disappear once a patient had described the focal event in detail. Pennebaker (1982) expanded on this idea by providing an explanation for the effects of EW with the general model of inhibition. This purports that, following a traumatic experience, many people may be either unable or unwilling to talk about or share their experience with others for fear of shame, disapproval or punishment. Pennerbaker et al, 1990 built on this idea by suggesting that actively inhibiting ones thoughts and feelings can be harmful since it places cumulative stress on the body, also activating the autonomic nervous system and putting strain on physiological functioning. This may then have a long-term negative impact on health through increased vulnerability to stress-related illness. By default, this implies disclosure of trauma-related thoughts and feelings can reduce stress, promote good health and encourage positive wellbeing. The findings from Pennebaker & Beall's (1986) seminal study (described above) support this hypothesis but a number of studies have since challenged the theory. In one example, Greenberg (1995) asked participants to write about either a real or imaginary trauma. Contrary to prediction, both groups had similar rates of reduced illness-related doctor visits, therefore contradicting the idea that one has to write about their personal thoughts and feelings connected to an event, in order to acquire the benefits.

More recently, Pennebaker and others have suggested that emotional expression does more than prevent the psychosomatic impact of stress, but believe it is also important in facilitating cognitive processing. This thinking occurred as a reaction to participants reporting that one helpful aspect of writing was allowing them to gain insight (Pennebaker et al, 1990). Cognitive processing refers to the process of organising, assimilation and discovery of meaning for a memory that results from talking about or confronting an upsetting event. This method allows individuals to simplify complex experiences, gain insight and control and integrate memories into

their schema, therefore freeing up energy previously devoted to inhibition, which can be utilised more efficiently in the body. To further examine this, Pennebaker (1993) developed a computerised text-analysis programme to investigate key words used during writing exercises. Findings were in-line with the cognitive processing theory, showing that those who had benefited most had increased their use of causation and insight words during the course of writing. In other words, those who benefitted seemed to begin with poorly organized descriptions and transformed them into coherent stories within a linguistic structure. This was therefore hypothesised to be a crucial underlying mechanism to the success of EW. However, a recent study by Cresswell et al (2007) failed to find evidence to support this theory (see below).

Contemporary researchers have put forward alternative theoretical explanations. Some have explained the effects in the context of self-regulatory theory. For example, Cameron and Nicholls's study (1998) used a modified version of the writing exercise designed to promote self-regulation. Students described problems they encountered in college and generated ways to fix problems, which produced the same benefits as EW. King (2001) also reported writing about one's 'best possible self' produced reductions in illness visits of a similar effect size to EW about trauma. Lepore, Greenberg, Bruno and Smyth (2002) explained how experimental disclosure can be thought of as a mastery experience, allowing people to observe themselves expressing and controlling their emotion, and providing them with a stronger sense of self-efficacy for emotional regulation. Furthermore, a recent study found that self-affirmation may act as psychological mechanism for positive effects of EW on aspects of health in early-stage breast cancer survivors (Cresswell et al, 2007). The authors claimed that, rather than increasing self-efficacy, self-affirmation acted as a stress buffer.

The social integration model has also been posited as a possible theoretical framework. This argues that disclosure affects the way people interact with their social world, consequentially influencing health and well-being. Results from Gellaitry et al's study (2010), as cited earlier, which illustrated the positive effect of EW on perceptions of social support, add credence to this theory. However, this idea is very new and has only been tested in handful of studies.

Finally, exposure theory of EW argues the expression of thoughts and feelings regarding an upsetting event, is similar to exposure (or flooding therapy) which is commonly recommended for treatment of anxiety-based disorders such as phobia

or post-traumatic stress disorder. This is grounded in the principle that, when a person repeatedly confronts or describes an experience, it is similar to reliving the thoughts and feelings about the experience, which should lead to extinction of such thoughts over time. However, support for this theory has been mixed (Lepore & Smyth, 2002).

Recently, Smyth and Pennebaker (2008) have stated "there is probably no single theoretical process that can explain the findings" (p.3). However, they highlight the general agreement that EW leads to emotional change and accumulating evidence in support of the process of habituation. They conclude that EW seems to affect different people across different dimensions.

1.8 Summary and Measuring Distress

To summarise, CKD is a progressive disease which coincides with a gradual reduction in kidney functioning which can lead to kidney failure or ESRD. When this occurs, patients must adhere to 'RRT' in some form, with HD currently the most popular modality. The HD treatment regime is extremely intrusive and burdensome for patients and many experience high levels of psychological distress, encompassing symptoms of depression and anxiety, as a result. Patients who suffer from ESRD and co-morbid depression have a lower QOL and higher mortality rate. The pathway between depression and poor outcomes is unclear but illness beliefs or perceptions have been proposed to play a role (in line with the CSM model) and have been shown to have a significant effect on outcomes. A number of interventions have been designed and tested in order to improve levels of depression and maladaptive illness perceptions, with some positive results. EW is a novel intervention which has been successfully applied to many clinical health settings, and has proved helpful in relation to many physiological and psychological health outcomes. However, no study to date has evaluated the effects of EW on patients being treated for kidney failure with HD.

As described above, much of the research in this field to date has focussed on the causes and impact of clinical depression. Due to the fact that EW is designed to target well-being, rather than depression as such, this study was designed to assess the impact on levels of general psychological distress. In addition, recent advances in psychometrics have indicated that bifactor models exist for many conventional depression measures. For example, a study by Martin, Tweed & Metcalfe (2004) deduced that the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) was unable to accurately and robustly assess independent

but related domains of anxiety and depression, since they both correlate with a more broad, general factor of 'distress'. These findings, alongside the fact that this study was interested in detecting patients with sub-clinical levels of distress, meant that the most popular measure for assessing psychological well-being, the General Health Questionnaire-12 (GHQ-12; Goldberg, 1988), was selected as the primary outcome measure. It was thought this would be the best way of capturing those patients struggling with mood, as well as other social factors, but who are not clinically depressed or anxious since such patients may be better suited to higher intensity interventions, such as one-to-one psychological therapy.

1.9 Aims and Hypotheses

This study was a feasibility study with a related series of questions by which feasibility was evaluated. Firstly, it was thought important to examine the characteristics of the proposed outcome measure, and thereby establish the correlates of psychological distress within the ESRD patients undergoing HD. Secondly, several questions related to recruitment and retention of participants throughout the study process. Thirdly, safety and acceptability of the EW procedure was investigated, and finally, preliminary outcomes of using EW with this population were used to judge potential clinical efficacy. The research questions can thus be outlined as follows:

1) What factors are associated with psychological distress within the HD population?

2) In terms of recruitment and retention rates:

    i. What number of patients will agree to be screened?

    ii. What proportion of patients will be screened as eligible for the writing intervention (i.e., agree to screening and score 3 or above on the distress measure)?

    iii. What number will agree to randomisation?

    iv. What proportion of patients will adhere to the task instructions and complete the writing task fully?

    v. What proportion of patients will drop out before follow-up at 3 months?

vi. Is the sample representative of the general dialysis population?

3) In terms of acceptability and safety of the intervention:

   i. Is it possible to implement the intervention with this client group?

   ii. Is the intervention clinically relevant and generally acceptable to participants?

   iii. Are there reports of distress or other problems as a result of taking part in the writing task?

4) In terms of preliminary outcomes, within the context of a small study:

   i. What evidence is there for the likely effect of the intervention on the primary outcome of psychological functioning (as indicated by psychological distress)?

   ii. What evidence is there for the likely effect of the intervention on the secondary outcome of physiological functioning (as indicated by blood pressure)?

In relation to question 1, it was hypothesised that higher levels of distress would be associated with negative illness perceptions, high levels of fatigue, pain and depression.

Questions 2 and 3 were purely exploratory questions so no hypotheses were made.

In relation to question 4, it was hypothesised that the patients randomised to the EW group would show improvements in psychological and physiological health at follow-up, in comparison to those randomised to the neutral writing group. Specifically, it was predicted that patients would report reduced levels of psychological distress, as measured by the General Health Questionnaire (Goldberg, 1988), and would have reduced blood pressure results, at 3 months post-EW intervention.

2.0 METHODS

2.1 Design

There were two phases to the study (screening phase and trial phase) which followed two different designs.

2.1.1 Screening phase

The first phase consisted of screening participants for clinical levels of distress with an additional aim of determining which factors were associated with psychological distress. A cross-sectional, retrospective questionnaire survey design was used and the main dependent variable was psychological distress as measured by the GHQ-12. Independent variables consisted of the factors investigated as potential predictors of distress. These were demographic variables (gender, age, marital status, living arrangements and employment) clinical variables (years on dialysis, transplant history and co-morbidity), symptom variables (fatigue and pain) and illness perceptions. Despite being a similar construct to distress, depression was included as an additional variable, in order to look at its relationship with distress. The study collected quantitative data for the variables mentioned above.

2.1.2 Trial phase

The second phase aimed to determine the recruitment and retention rates, acceptability and safety and preliminary outcomes of the EW intervention. This phase used a randomised controlled trial (RCT) design with two conditions (EW and control) and 3 follow-up assessments which took place pre-intervention, and at 1 week and 3 months post-intervention. Figure 2 below shows a schema of the study design.

Recruitment and retention rates were determined by recording the number of patients who were eligible for screening, the number who agreed to be screened, the number who agreed to randomisation following screening, the number who were correctly able to adhere to the writing instructions, and the number who completed questionnaires post-intervention at 3 month follow-up. Brief qualitative data was also collected by asking participants open questions about how useful/helpful they found the writing, once their 3-month follow-up was completed and a fidelity check was completed, in order to determine acceptability. Safety was established by recording any heightened distress and preliminary outcomes by analysing effects on primary and additional outcome measures.

The main dependent variable for assessing clinical efficacy was self-reported distress, and blood pressure was a secondary outcome variable. The main independent variable in this phase was the condition patients were randomised into.

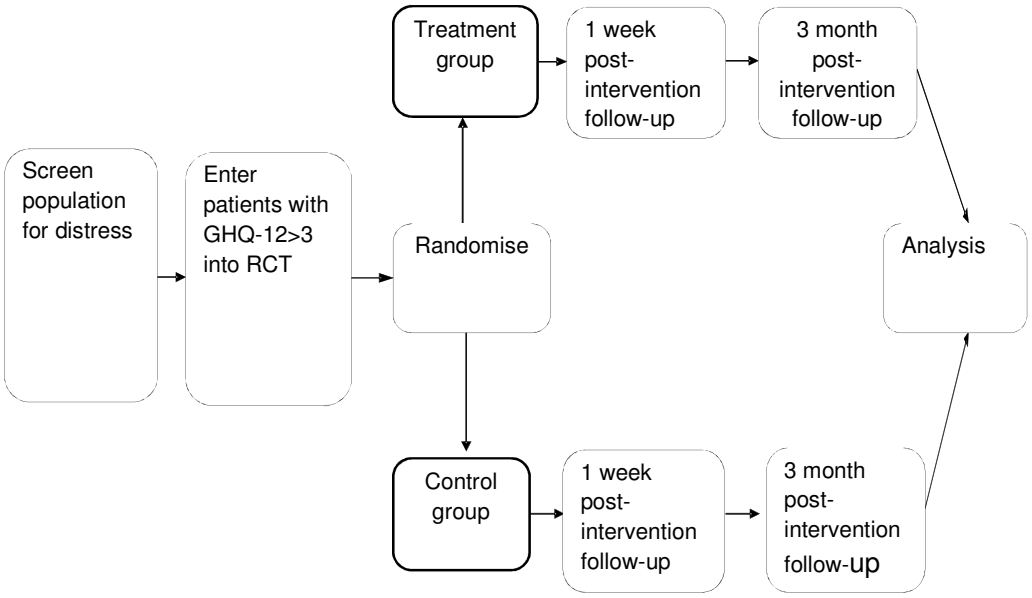

Figure 2. Schema representing study design

2.2 Sample

The participants for this study were patients undergoing haemodialysis treatment recruited from both hospital-based and satellite dialysis units (Astley Cooper, Borough, Camberwell and Tunbridge Wells Dialysis Units), all managed by Guys & St Thomas' NHS Foundation Trust. Exclusion criteria (for both the screening and trial phases) included patients under the age of 18, those with significant visual or physical impairment preventing completion of the questionnaires, inability to speak or write in English, known cognitive impairment, and documented history of psychiatric illness including severe depression (identified as being under the care of a psychiatrist). Those who were actively completing psychological treatment for low mood were also excluded to avoid the EW intervention interfering with treatment. To be included in the RCT phase of the study, patients needed to demonstrate significant distress defined as a score of 3 or more on the GHQ-12.

2.3 Measures

The measures were administered in the form of a questionnaire booklet (see Appendix H) comprising of the main outcome measure variable (psychological

distress), as well as the additional variables of self-reported symptoms (pain and fatigue), illness perceptions and depression. These are detailed below.

2.3.1 Psychological distress

Psychological distress was captured using the GHQ-12 (Goldberg, 1988), a self-administered screening instrument designed to measure levels of general distress in the community and medical settings. It focuses on two main classes of experience; inability to carry out one's normal healthy functions and, emergence of new distressing phenomena (Goldberg & Williams, 1988). The 12-item version is a short form of the original GHQ-60 (Goldberg, 1972) and is widely used for screening common mental disorders (Goldberg et al, 1997). This version consists of 12 questions asking respondents to rate how much they have experienced various symptoms of psychological well-being over the past few weeks. Answers are given on a four-point scale, with higher scores indicating greater distress (Goldberg, 1992). It is thought to be a highly accurate measure for discriminating 'cases' (those with probable non-psychotic mental health problem) from 'non-cases' (those with no significant non-psychotic mental health problem) (Goldberg et al, 1997). Werneke, Goldberg, Yalcin & Ulcin (2000) investigated the psychometric characteristics of the GHQ-12 using a large sample size factor analysis and concluded it to be a reliable instrument for screening and case detection in all clinical settings. However, although the GHQ has proven to be a sensitive and specific predictor for mental disorder, its relationship with a clinical diagnosis of mental disorder is thought to vary for different subgroups. It has therefore been suggested the GHQ-12 score be interpreted as an indicator of general mental distress rather than of any specific mental disorder (Verhaak, Heijmans, peters & Rijken, 2005)

There is some debate about the best method of scoring the GHQ-12. Three different methods have been used; the standard binary 'GHQ method' which assigns a score of 1 to symptomatic responses and 0 to non-symptomatic responses (0,0,1,1), the Likert type which assigns scores of 0-3 to each item response (0,1,2,3), and the 'C-GHQ type'. The latter is less frequently used and involves scoring items that measure health as usual but scoring items reflecting illness as 0,1,1,1. In a study comparing the GHQ-12 and GHQ-28 across different cultures, Goldberg et al (1997) found that the Likert method was less valid than the standard GHQ method for the GHQ-12 and that the C-GHQ method was the least valid for both questionnaires. Both the binary and Likert type methods of scoring were used for this study.

Goldberg and Williams (1988) suggest that the threshold criteria for 'caseness' should be based on previous studies that have investigated a similar population cohort. Studies validating the use of the GHQ-12 with patients within a variety of general health care settings have indicated a cut-off score of 2 or 3 to be optimal (using the standard GHQ method of scoring) (e.g., Jacob, Bhugra & Mann, 1997; Plummer et al, 2000). Since no study is yet to validate the GHQ-12 to detect distress for dialysis patients, the threshold score used in this study was based on a recent study which used the GHQ-12 with a sample of employees from the NHS (Hardy, Shapiro & Haynes, 1999). This found that the best threshold score was 3/4 (with a specificity of 0.84 and sensitivity of 0.74).

2.3.2 Illness perceptions

The Brief Illness Perceptions Questionnaire (BIPQ) was used to assess individual illness perceptions. This questionnaire, which is a shorter version of the original Illness Perception Questionnaire (IPQ; Weinman et al, 1996) applies a single-item scale approach and has been widely used to assess five dimensions within a cognitive representation of illness. A revised version of this measure known as the IPQ-R (Moss-Morris et al, 2002) extended the original scale by adding more items and consisted of 80 items in total. The brief version was developed by Broadbent et al in 2006 and generally consists of just 9 items; 8 new items plus part of a causal scale previously used in the IPQ-R. Five of the items assess cognitive illness representations (consequences, timeline, personal control, treatment control and identity), two of them assess emotional representation (concern and emotions) and one item assesses illness coherence. The causal representation is assessed via an open-ended response item which asks the patient to list the three most important causal factors in their illness. The psychometric properties of this measure have been assessed using samples from several illness groups, including renal patients (Broadbent, Petrie, Main & Weinman, 2006). The results indicated good test-retest reliability, validity and moderate to good associations between the Brief IPQ and the IPQ-R on all equivalent dimensions. The advantages this brief version offers are brevity and speed of completion for patients, as well as easy interpretation of scores. Increases in item scores represent linear increases in the dimension measure. It is standard practice to adapt the wording of the BIPQ to make it relevant to the sample population (i.e., "your illness" was replaced with "your kidney problem"). In addition, the version used in this instance omitted the item measuring 'identity' beliefs. This was due to the fact that this would ask about the number of symptoms of the illness experienced by the patient, which would potentially inflate

the correlation between self-reported symptoms (i.e., fatigue and pain) and the total BIPQ score.

Items 3, 4 and 6 (measuring personal control, treatment control and coherence beliefs respectively) of the BIPQ were reverse scored and so had to be transformed in the data file, prior to analysis. This meant that higher scores equated to less positive views of illness. Internal reliability of the scale was found to be acceptable ($\alpha = 0.67$).

2.3.3 Depression

Numerous well-validated questionnaires are available for depression screening, one particularly popular measure being the 9-item depression module of the Patient Health Questionnaire (PHQ-9) which has been validated in 6000 patients (Spitzer, Kroenke & Williams, 1999). This self-administered questionnaire is designed to establish DSM-IV criteria-based psychiatric diagnosis of depression. The items are therefore derived from the DSM-IV classification system and pertain to; anhedonia, depressed mood, trouble sleeping, feeling tired, change in appetite, guilt or worthlessness, trouble concentrating, feeling slowed down or restless and suicidal thoughts. The two-item version (PHQ-2) is a shortened version which includes the first two items of the PHQ-9 measuring symptoms of anhedonia and low mood. It asked respondents to estimate the frequency of these 2 symptoms over the past 2 weeks with 4 response options ranging from “not at all” to “nearly every day”. Although it lacks the validity and reliability strength of the PHQ-9, this brief measure has demonstrated good criterion and construct validity when used with primary care patients and its simplicity make it a suitable screen for depression in this study population. The PHQ-2 scores can range from 0-6 and a cut-off score of 3 or above is considered a reliable indicator of clinically significant depression (Kroenke, Spitzer & Williams, 2003). A recent study by Gyamlani et al (2011) provided support for the validity of the PHQ-2 in patients with CKD through observing its correlation with CES-D results and functional status.

2.3.4 Pain

The Visual Analogue Scale (VAS) is a commonly used pain rating scale. It is presented as a 10 cm line, anchored by verbal descriptors, which are usually “no pain” and “worst imaginable pain”. The respondent is asked to place a mark on the line to indicate pain intensity. A review of this measure in comparison to two other commonly used pain rating scales (Numerical Rating Scale and Verbal Rating Scale) suggested that statistically, the VAS is the most robust as it can provide ratio

level data as well as proving to be reliable and valid (Williamson & Hoggart, 2005). It has also been found to have a high degree of sensitivity or discriminating capacity, superior to that of other scales (Jamieson et al, 2002).

2.3.5 Fatigue

The Chalder Fatigue Scale (CFQ) is a brief self-rated instrument that measures the symptoms of mental and physical fatigue. The 14-item version was developed to measure fatigue in chronic fatigue syndrome (CFS) patients and component analysis revealed good evidence for the distinction between the two constructs of physical and mental fatigue (Chalder et al, 1993). Suspected overlap between the items prompted Morriss, Wearden & Nullis (1998) to analyse the scale further, revealing four constructs of fatigue in CFS patients (subjective cognitive complaints and effortful cognition, difficulties maintaining sleep, strength and aerobic performance and depression). These study results supported the use of a shorter 11-item version which omits some items that strongly correlated with symptoms of depression. This study used the 11-item scale and was scored 'bimodally' (where response options "less than usual" and "no more than usual" are given scores of 0 and "more than usual and "much more than usual" are given scores of 1). Using this method, total fatigue score is obtained by adding the scores for all items (with a range of 0–11) and a score of 4 or more is thought to indicate 'caseness'. The scale has proved to be both valid and reliable when used with general practice attenders and has a high degree of internal consistency (Cronbach's alpha of 0.89; Chalder et al, 1993).

2.3.6 Demographic and clinical variables

The demographic variables were collected via a questionnaire (see Appendix G) at baseline, and included age, marital status, living arrangements and employment status. Clinical variables were recorded using a prof forma (see Appendix F) both at baseline and follow-up via electronic medical records and represent those collected as standard as part of routine care. They included haemoglobin, serum albumin, C-reactive protein, Kt/V, potassium, serum phosphate, ferritin, PTH, blood pressure, dialysis vintage and past transplant history.

Co-morbidity burden at baseline was quantified from medical notes using the method described by Davies, Philips, Niash and Russell (2002) by a consultant nephrologist. One point for each of the following conditions was assigned to: ischemic heart disease (defined as prior MI, angina, or ischemic changes on ECG), left ventricular dysfunction (defined as clinical evidence of pulmonary oedema not

due to errors in fluid balance, or history of congestive heart failure), peripheral vascular disease (includes distal aortic, lower extremity, and cerebrovascular disease), malignancy, diabetes, collagen vascular disease, and other significant pathology. Patients were grouped into co-morbidity categories according to the number of co-morbidities present; 'none' (score of 0), 'medium' (score of 1-2) and 'high' (score of 3 or more).

2.4 Procedure

Patients who met the inclusion criteria were identified by a member of the clinical team responsible for their care at each of the dialysis sites. A member of the clinical team initially approached the patients to ask their permission to be contacted by the research team. Those that gave permission were approached by a researcher, who informed them verbally that a scientific study was on going, and that its purpose was to "learn more about how individuals deal with dialysis treatment" and were provided with the Patient Information Sheet (see Appendix C). This specified that, if they were to consent, they would be asked to complete some questionnaires and then may be randomised into one of two writing conditions that would involve writing about aspects of their renal problem and dialysis treatment on three consecutive clinic days. Once patients signed the consent form (see Appendix D), which included no mention of the expected benefits from the writing sessions, they were administered the baseline screening questionnaires. Those who met the screening cut-off for distress were randomly assigned to either the EW or control condition. Patients were randomised using a computerised stratified block randomisation system with fixed block sizes, run by the KCTU randomisation service. The stratification factor used was gender. Participants were blind to condition assignment and therefore not told which condition they had been randomized to. Once randomization was performed, no change to treatment allocation occurred. In order to monitor potential distress as a result of writing, the chief investigator remained un-blinded to condition assignment.

Following randomisation, each eligible participant was approached on their next dialysis day, and asked again whether they would be happy to complete the writing exercise. They were then presented with standardised instructions, according to their group condition, and left alone to complete the writing task (whilst dialysis treatment was taking place). Patients were provided with a pen and paper to write on. The writing sessions were stopped and writing sheets were collected after approximately 20 minutes. This procedure was repeated during the patient's next

two dialysis sessions. Once all three writing sessions were completed, the PHQ-2 questionnaire was re-administered at 1 week follow-up, to check for significant depressive symptoms. All psychosocial outcome questionnaires were then repeated after 3 months.

Recent studies showing effectiveness of this intervention with cancer patients have instructed participants to write about their illness experiences rather than any previous trauma (e.g., Corter & Petrie, 2011). This study followed a similar method which meant that the two sets of instructions emulated those typically used in studies of EW, but modified so that they were disease-specific. The EW group were asked to write about their thoughts and feelings connected with dialysis treatment. The control group were asked to write about unemotional neutral topics, related to the patient's day-to-day management of the disease, as suggested by Pennebaker (1989). The instructions are outlined below.

EW condition

"What we would like you to write about for these three sessions are your thoughts and feelings regarding your experience of undergoing dialysis treatment. We realise that individuals undergoing this treatment experience a full range of emotions and we want you to focus on any of them or all of them. You might think about all the various feelings and changes that you experienced before starting the dialysis treatment, after it had started and at present. Whatever you choose to write, it is important that you really focus on feelings, thoughts, or changes that you have not discussed in great detail with others. You might also relate your thoughts and feelings about your experiences of dialysis treatment to other parts of your life – your childhood, people you love, who you are or who you want to be. Again, the most important part of your writing is that you focus on your deepest emotions and thoughts. The only rule we have is that you write continuously for the entire time. If you run out of things to say, just repeat what you have already written. Don't worry about grammar, spelling or sentence structure. Don't worry about erasing or crossing things out. Just write."

Neutral condition

"What we would like you to write about for these three sessions are detailed accounts of the facts about different features of your life in relation to your dialysis treatment. We are interested to know the specifics about how lifestyle differs among individuals undergoing dialysis treatment. Therefore, it is important you try to

provide a detailed account of the facts concerning the different topics outlined below. We realize that individuals with undergoing dialysis treatment experience many emotions, but in your writing we want you to focus only on the facts, not on your emotions.

In the **first session**, we would like you to focus the subject of your writing on diet. You might write about what advice you were given about diet when you started dialysis treatment and then a detailed description of what you have eaten over the last week.

In the **second** session, we would like you to focus the subject of your writing on exercise and movement. You might write about what advice you were given about exercise when you started dialysis treatment and then a detailed description of your exercise and movement in a typical week.

In the **third and final session**, we would like you to focus the subject of your writing on medication. You might write about what medication you took leading up until the start of dialysis treatment, and how this has changed over time, including the names and dosages (if you know them)."

2.4.1 Experimental manipulation check

An independent rater not involved in the study and unaware of condition membership judged whether each participant's writing session pertained to the EW or control condition instructions. This was cross-checked with actual treatment allocation.

All participants were randomly assigned to the experimental conditions following completion of baseline measures.

2.5 Ethical Considerations

This study was approved by the NRES Committee London – Camden and Islington (study reference 12/LO/1858), and research governance was received by Guy's and St Thomas' Research and Development Office (registration number RJ113/N009). The approval letters for both can be seen in Appendices A and B.

The main ethical considerations were related to the possibility of heightened distress as a result of taking part in the writing task and being assigned to the EW condition. This task asked participants to reflect on deep thoughts and feelings, many of which may have been difficult or painful, or which they had not expressed to others. Some authors have speculated there is a risk of short-term increase in

distress occurring (e.g., Hockemeyer et al, 1999). In order to address this, participants were followed up after one week and asked to complete the PHQ-2 questionnaire. At this point, they were asked about their initial reactions. If a significant rise in emotional distress was detected, they were identified to the consultant nephrologist for further assessment or onward referral to the Renal Psychology Service (who were aware of the research taking place).

Any patient identifiable data was stored securely in accordance with clinical governance requirements. The participants' writing scripts and experimental data from questionnaires were stored anonymously using a patient identifier number. Letters were sent to patients' GPs to inform them of their participation in the study (see Appendix E).

2.5.1 Piloting

Another ethical consideration was the possibility of increased discomfort as a result of the physical burden of writing whilst undergoing dialysis. Therefore, following the review by the Renal Project Board Steering Committee, the procedure was piloted for feasibility with permission from a consultant nephrologist, and in accordance with the Guys & St Thomas' Trust policies and procedures. This involved approaching a small number of patients and asking them about the practicality of writing whilst undergoing dialysis and whether they had any concerns. A few patients were also asked to write about a topic of their choice for ten minutes. Most patients were happy to comply and able to complete the writing without discomfort. The main problems identified were feeling too tired to write or the fistula being located in their writing arm, making it difficult to write. As a result, instructions for completing the writing task were altered so participants were offered to take a break half way through the writing, if required. In addition, patients were given the option of writing during the second half hour of dialysis, giving time for them to settle and so as not to interfere with the usual medical procedure. No further amendments to the procedure were needed. The questionnaires did not require piloting since they were considered sufficiently validated for use with this population.

2.6 Statistical Analyses

SPSS Statistical Package (version 21.0) was used for the analysis of the study results. Descriptive statistics were used to illustrate the demographic, clinical and psychological characteristics of the sample. For the initial cross-sectional phase, correlational analyses were used to investigate which of the variables were associated with the main outcome measure of distress. Those variables which

correlated with distress were entered into a hierarchical regression in order to explore how strongly they were able to predict distress, whilst taking covariance into account. An additional regressional analysis was completed to investigate the relationship between individual illness perceptions and distress in more detail.

For the second trial phase, recruitment and retention rates were established through the procedure outlined previously (see section 2.1.2). Fidelity of the randomisation conditions was established using an independent rater who judged group condition from the writing scripts. Potential clinical efficacy was determined by analysing differences between group means at the 3-month follow-up time point and a regression was carried out to explore whether the group differences were able to predict changes to distress over time. Since this was a feasibility study, the sample size meant that the statistical tests lacked sufficient power to show statistically significant differences. Therefore, effect sizes were used to provide an indication of difference between groups. Cohen (1988, 1992) has made some suggestions about what constitutes a large (0.8), medium (0.5) and small (0.2) effect, and these are generally accepted conventions for specifying the magnitude of effect size within research.

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3.0 RESULTS

3.1 Sample Characteristics

The sample (n=97) comprised of 51 males and 46 females with a mean average age of 62 years (median=68, SD=16, range 26 – 87). At baseline, the majority of participants were married or living with a partner (n=50, 51.5%) with the second biggest proportion identified themselves as 'single' (17.5%). In addition, the majority of participants (n=62, 57.7%) were living with at least one other person (26.8% with a partner; 20.6% with a partner and children; 10.3% with other relatives) and 32% were living alone. In terms of working status, a relatively small number (n=13, 13.4%) of participants were in employment (6.2% full-time and 7.2% part-time), approximately one third (34%) were unable to work due to poor health, 46.4% were retired and the remainder were either unemployed (3.1%) or full-time home-makers (1%).

The sample characteristics can be seen in Table 1.

Table 1. Frequency data for demographic characteristics of the sample

	N	(%)
Gender		
Males	51	52.6
Females	46	47.4
Relationship status		
Married	46	47.4
Living with partner	4	4.1
Widowed	8	8.2
Divorced	10	10.3
Separated	6	6.2
Single Parent	2	2.1
Never Married	2	2.1
Single	17	17.5
Other	2	2.1
Living arrangements		
Live alone	31	32
Live with partner	26	26.8
Live with partner and children	20	20.6
Single parent with children	10	10.3
Live with other relatives	10	10.3
Employment status		
Working full-time	6	6.2
Working part-time	7	7.2
Retired	45	46.4
Full-time home-maker	1	1
Unemployed	3	3.1
Not working due to ill health	33	34
Other	2	2.1

3.2 Disease-Related Information

The average dialysis vintage for this sample was 5.8 years (SD=6.6, range 0-37). In terms of transplantation, 20.6% (n=20) had undergone at least one previous kidney transplant and 79.4% had not. In addition, 32% were on the transplant list, 61.9% were not on the list and 6.2% were unaware of their listing status.

With regards to co-morbidity, 66% of the sample had a 'medium' co-morbidity burden (one or two co-morbid conditions), 18.6% had a 'high' co-morbidity burden (three or more co-morbid conditions) and 15.5% had no existing co-morbid conditions.

Descriptive statistics for clinical outcomes are shown in Table 2.

Table 2. Descriptive statistics for clinical outcomes

Clinical outcome	Mean (SD)	95% CI
Hb g/dl	10.5 (1.2)	10.2-10.7
Albumin g/dl	40.0 (5.6)	38.8-41.0
Kt/V	1.8 (0.5)	1.7-1.9
Phosphate mg/dl	1.5 (0.6)	1.4-1.6
SBP mmHg	137.7 (22.0)	133.3-142.2
DBP mmHg	74.3 (14.3)	11.7-16.8
Potassium mmol/l	8.8 (23.3)	4.6-14.2
PTH pg/ml	404.7 (360.7)	332.4-479.2
Ferritin ng/ml	787.1 (575.4)	676.8-902.0

SD, standard deviation; CI, confidence interval; Hb, haemoglobin; Kt/V, measure of treatment adequacy; SBP, systolic blood pressure; DBP, diastolic blood pressure; PTH, parathyroid hormone

C-reactive protein (CRP) is recorded differently in medical records to other clinical outcomes. It is recorded as an exact value where the level is greater than 5 (suggesting inflammation) and recorded as '<5' (suggesting non-inflammation) when the level is less than five. For data analysis, CRP scores were therefore assigned values to denote high or 'inflamed' (CRP>5), and low or 'non-inflamed' (CRP<5) levels. According to these re-coded values, approximately half the sample was inflamed (51.5%) and half was non-inflamed (48.5%).

3.3 Self-reported Symptoms, Illness perceptions and Psychological Outcomes

3.3.1 Pain and fatigue

The mean ratings of pain intensity were 3.6 (SD=3.3) at rest and 3.9 (SD=3.4) when moving. The mean rating of pain unpleasantness was 4.2 (SD=3.5).

The mean fatigue score was 4.5 (SD=3.4). In terms of 'caseness' (denoted by a score of 4 or above), approximately two thirds of the sample was clinically fatigued (61.9%).

3.3.2 Illness perceptions

The total and subscale mean scores for the BIPQ are detailed in Table 3. The highest mean scores (and therefore the most negative illness perception) was for item 2, which measured timeline (mean=7.8, SD=3.0).The lowest mean scores (and therefore most positive illness perceptions) were for item 4 which measured treatment control (mean=1.8, SD=2.5) and item 6 which measured treatment coherence (mean=2.4, SD=3.0). The average total illness perception score was

35.4 (SD=10.5). The total illness perception score was also calculated excluding 'concern' and 'emotions' items, since these are measuring emotional representations, which are likely to correlate with the other psychological variables (such as distress and depression). This new scale could therefore be considered a measure of illness cognitions only, and had an average score of 23.9 (SD=7.1). This new score indicating illness cognitions was used in subsequent analysis.

Table 3. Brief Illness Perception Questionnaire (BIPQ) scores

BIPQ Item	Mean (SD)	95% Confidence Interval
IP1, Consequences	5.9 (3.4)	5.4 - 6.7
IP2, Timeline	7.8 (3.0)	7.1 – 8.3
IP3, Personal control	5.8 (3.1)	5.3 – 6.5
IP4, Treatment control	1.8 (2.5)	1.4 – 2.4
IP5, Concern	6.4 (3.5)	5.8 – 7.1
IP6, Coherence	2.4 (3.0)	1.8 – 3.0
IP7, Emotions	5.0 (3.7)	4.4 – 5.8
Total Score	34.9 (10.8)	33.4 – 37.5
Total Score (excluding Concern and Emotions)	23.9 (7.1)	22.4 – 25.2

3.3.3 Depression

The median total PHQ-2 score was 1 (interquartile range=2). In terms of 'caseness' (denoted by a score of 3 or above), 23.7% of the sample was clinically depressed.

3.3.4 Psychological distress

For the purposes of analysis, the Likert-types scores of the GHQ-12 were used since this provides a wider variation of scores and therefore added depth to the analysis. The average total GHQ-12 score was 13.3 (SD=6.3) out of a possible 31. In terms of 'caseness' (denoted by a score of 3 or above when using binary scoring), 44.3% of the sample was clinically distressed.

3.4 Correlates of Distress

3.4.1 Univariate analysis

In order to examine the association between clinical, demographic and psychological variables with the main outcome variable of psychological distress, correlations were generated between these variables and the GHQ-12 scores. These correlations are reported in Table 4.

Table 4. Pearson's r correlations between demographic, clinical and psychological outcome measures

		1	2	3	4	5	6	7	8
1	GHQ-12 Score	1							
2	Age	-.235*	1						
3	Years on dialysis	-.027	-.148	1					
4	BIPQ Score	.382**	-.174	-.016	1				
5	CFQ Score	.616**	-.134	-.084	.360**	1			
6	VAS-Pain Score (at rest)	.376**	-.193	.138	.316**	.400**	1		
7	VAS-Pain Score (rating)	.379**	-.095	.110	.239*	.444**	.726**	1	
8	PHQ-2 Score	.712**	-.391**	-.041	.363**	.513**	.565**	.485**	1

*p<0.05, **p<0.01; GHQ-12, General Health Questionnaire; BIPQ, Brief Illness Perceptions Questionnaire; CFQ, Chalders Fatigue Scale; VAS-Pain, Visual Analogue Scale-Pain; PHQ-2, Patient Health Questionnaire.

It can be seen that significant correlations exist between the GHQ-12 scores and illness perceptions, fatigue, pain at rest, unpleasantness of pain and depression (as measured by the BIPQ, CFQ, VAS-Pain and PHQ-2 scores). GHQ-12 scores also significantly correlated with age, although they did not correlate with any of the clinical variables collected. Scatter plots showing correlations between GHQ-12 scores and BIPQ, CFQ, VAS-Pain and PHQ-2 scores are shown in Figures 3, 4 and 5.

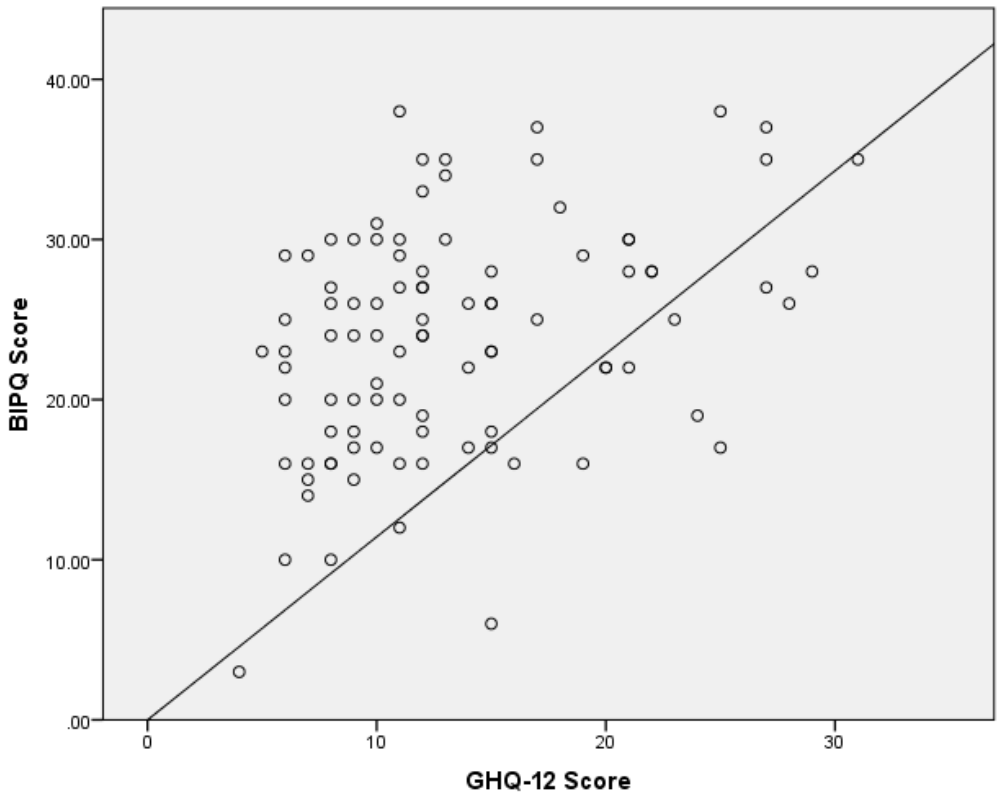


Figure 3. Scatter plot showing correlation between BIPQ and GHQ-12 scores

The above scatter plot shows the positive correlation ($r=.382$, $p<0.01$) between illness perceptions (BIPQ) and distress (GHQ-12) scores. If we were to interpret Pearson's correlation coefficient as an effect size, according to Cohen (1988, 1992), $r=0.38$ represents a medium effect size, accounting for roughly 9% of the total variance in the data.

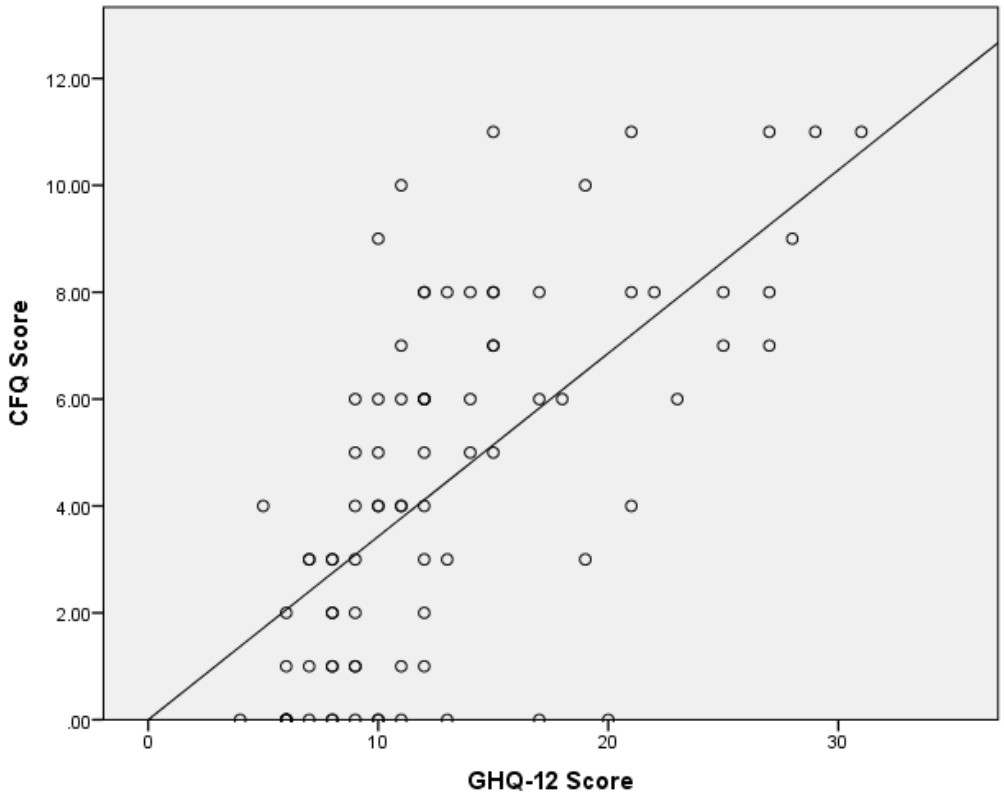
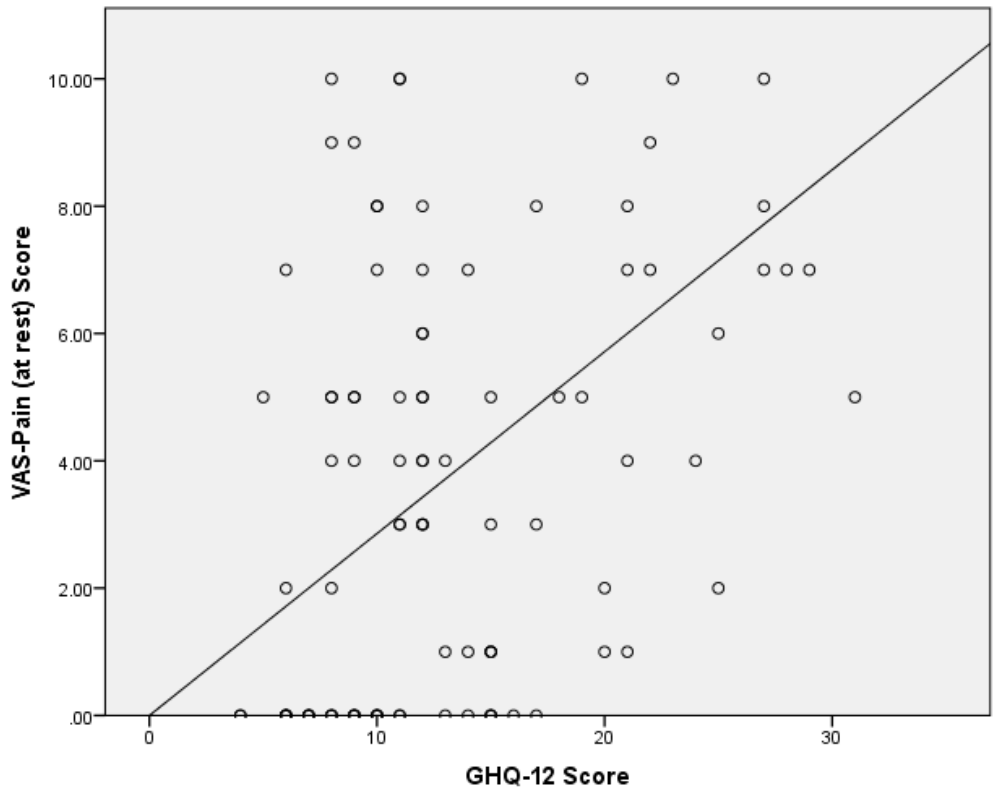


Figure 4. Scatter plot showing correlation between CFQ and GHQ-12 scores

The above scatter plot shows the positive correlation ($r=.616$, $p<0.01$) between fatigue (CFQ scores) and distress (GHQ-12 scores). Again, by interpreting the correlation coefficient as an effect size, $r=0.62$ would represent a large effect size, accounting for over 25% of the variance in the data. It is evident that a number of patients scored 0 on the CFQ measure.



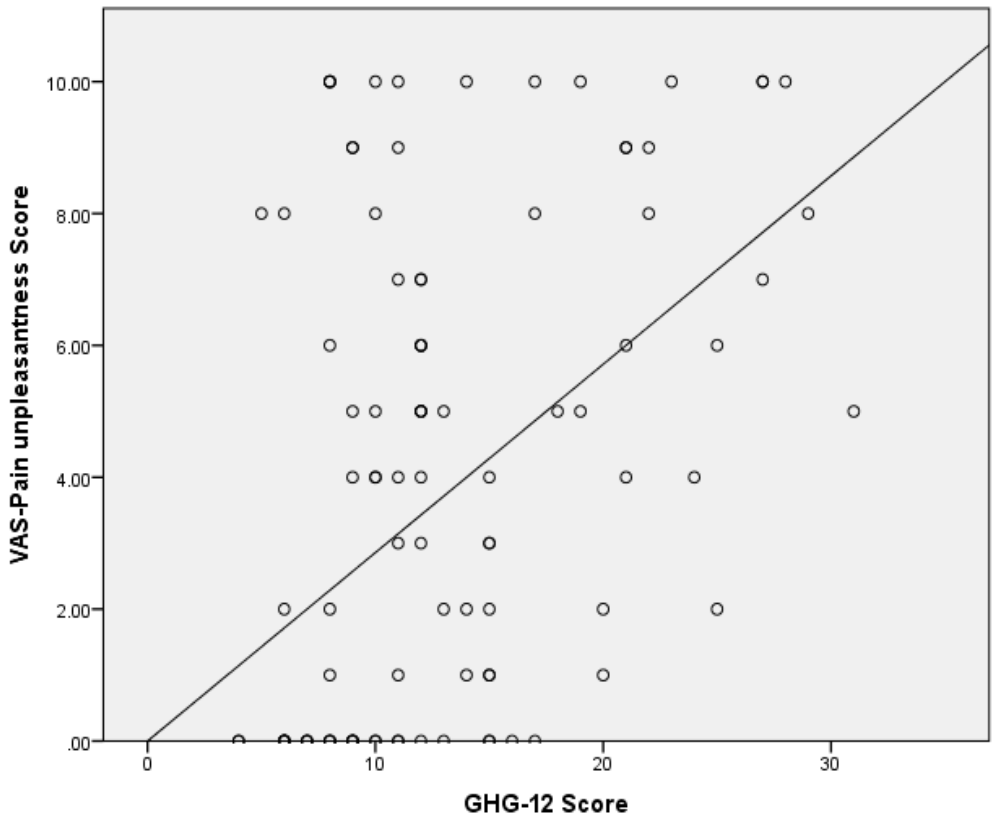


Figure 5. Scatter plots showing correlation between VAS-Pain (at rest and unpleasantness) and GHQ-12 scores

The above scatter plots show the positive correlations between ratings of pain at rest (r=.376, p<0.01) and ratings of pain unpleasantness (r=.379, p<0.01) (VAS-Pain scores) with distress (GHQ-12 scores). Neither of these ratings of pain correlated as strongly with distress as illness perceptions or fatigue, but both correlation coefficients would be considered medium effect sizes. The graphs also show a number of patients scored 0 on the VAS-Pain measure.

In order to test whether distress differed across any other demographic variables, appropriate statistical tests were carried out to compare groups. An independent samples t-test was used for the two-category variable (gender) and a one-way ANOVA was used for variables with more than two categories (relationship status, living arrangements). Cohen's d or eta squared (η^2) were also calculated for each result. The results of these analyses are reported in Table 5.

Table 5. GHQ-12 scores across demographic variables

Demographic Variable	Cases (n)	GHQ-12 mean score (SD)	Independent samples t-test or one way ANOVA result	Effect Size (Cohen's d or η^2)
Gender				
Male	45	14.09 (6.58)	t(94)=1.18, p=.240	d=0.24
Female	51	12.57 (6.02)		
Relationship status				
Married	45	13.31 (6.78)	t(94)=0.05, p=.957	d=0.01
Not married	51	13.24 (5.79)		
Living arrangements				
Live alone	31	13.16 (5.50)	t(94)=0.13, p=.898	d=0.02
Not living alone	65	13.34 (6.69)		

As can be seen in Table 5, distress scores did not vary significantly as a function of gender, relationship status, living arrangements, although there was a small effect size detected for gender (d=0.24).

Similar tests were carried out to compare the distress levels across groups with different clinical variables. Independent samples t-tests were carried out to establish if there was a significant difference between the GHQ-12 scores for inflamed and non-inflamed groups (according to CRP scores) and between those with and without transplant history. A one-way ANOVA was used to establish whether distress levels differed according to co-morbidity.

Table 6. GHQ-12 scores across clinical variables

Clinical Variable	Cases (n)	GHQ-12 mean score (SD)	Independent samples t-test or one way ANOVA result	Effect size (Cohen's d or η^2)
CRP				
Low (non-inflamed)	47	12.30 (6.28)	t(94)=-1.51, p=.135	d=0.31
High (inflamed)	49	14.22 (6.24)		
Transplant Hx				
Yes	20	12.75 (6.10)	t(94)=0.42, p=.674	d=0.11
No	76	13.42 (6.38)		
Co-morbidity				
None	15	11.33 (4.98)	*F*(2,93)=0.86, p=.428	η^2=0.13
Medium	64	13.59 (6.29)		
High	17	13.82 (7.36)		

As can be seen in Table 6, distress scores did not vary significantly as a function inflammation, transplant history or co-morbidity, although there was a small to medium effect size detected for levels of inflammation (d=0.31).

3.4.2 Multivariate analysis

A hierarchical linear regression was used to assess the ability of the symptom variables (fatigue and pain) and illness perceptions to predict levels of distress, after controlling for the influence of gender, age and co-morbidity.

Given the exploratory nature of the hypothesis, before the regression was carried out, the data was examined in order to satisfy normality assumptions. This meant creating histograms for age, GHQ-12, BIPQ, CFQ and VAS-Pain scores. In addition, the data was checked for multi-collinearity by examining correlations between the predictor variables. As is shown in Table 4, there is a strong correlation between VAS-Pain (at rest) scores and VAS-Pain (unpleasantness) scores (r=.726). This is to be expected since both scales measure a construct linked to pain. In addition, there is a strong correlation between PHQ-2 and GHQ-12 scores (r=.712). Again, this is unsurprising, since both scales measure depressive symptoms. However, no strong correlations (r>0.7) exist between illness perceptions, fatigue and pain at rest, suggesting no evidence of multi-collinearity which meant these factors were entered into the model. A substituted mean was used in statistical computation (for missing value, participant 1).

The results can be seen in Table 7. Gender, age and co-morbidity were entered at block 1, explaining 10.5% of the variation in distress levels, which was found to be significant (*F* change (4,89)=2.62, p=.040). After entry of illness perceptions, fatigue and pain at block 2, the total variance explained by the model as a whole was 45.6%, indicating that the symptoms and illness perception variables explain an extra 35.1% of the variance, which was found to be significant (*F* change (3, 86)=18.48, p=.000). In the final model, three variables were statistically significant, with age (standardised β=-.22, p=.012), illness perceptions (standardised β=.24, p=.013) and fatigue (standardised β=.44, p=.000) shown to be independent predictors of distress. The standardised beta (β) values show that as age increases by one standard deviation, GHQ-12 scores decrease by .22 standard deviations; as BIPQ scores increase by one standard deviation, GHQ-12 scores increase by .24 standard deviations and as CFQ scores increase by one standard deviation, GHQ-12 scores increase by .44 standard deviations.

Table 7. Linear model of predictors of distress, with 95% percentile confidence intervals reported in parethenses

	b	SE B	β	p
Step 1				
Constant	19.10 (12.92, 25.29)	3.11		p=.000
Gender	-1.64 (-4.19, 0.91)	1.28	-.13	p=.204
Age	-0.11 (-0.19, -0.03)	0.04	-.27	p =.009
Co-morbidity1 (medium vs other)	2.19 (-1.35, 5.72)	1.78	.17	p =.222
Co-morbidity2 (high vs other)	3.05 (-1.28, 7.37)	2.17	.19	p=.165
Step 2				
Constant	9.11 (3.39, 14.83)	2.88		p=.002
Sex	-0.60 (-2.67, 1.48)	1.04	-.05	p=.569
Age	-0.09 (-0.16, -0.02)	0.03	-.22	p= .012
Comorbidity1	1.08 (-1.75, 3.92)	1.42	.08	p=.450
Comorbidity2	1.08 (-2.43, 4.60)	1.77	.07	p=.543
BIPQ Score	0.21 (0.04, 0.37)	0.08	.24	p=.013
CFQ Score	0.83 (0.48, 1.18)	0.18	.44	p=.000
VAS-Pain Score	0.15 (-0.19, 0.49)	0.17	.08	p=.379

B = Beta; β = Standardised Beta

Step1: R^2=.105, ΔR^2=.065, $F(4,89)=2.62$, p=.040

Step2: R^2=.456, ΔR^2=.412, $F(3, 86)=18.48$, p=.000

Since total BIPQ scores were shown to be a significant predictor of levels of distress, additional linear regressions were carried out to determine the predictive value of each individual illness perception. Each regression controlled for age, sex and co-morbidity.

The results for these additional regressions can be seen in Table 8. Only one of the individual illness perceptions was shown to significantly predict the variance in distress levels, which was item 1 measuring 'consequences' (b=0.95, β=.52,

p=.000), which accounted for 32.5% of the variance in distress scores. The β value indicates that, as the measure of perceived consequences increases (which implies a more negative perception) by one standard deviation, GHQ-12 scores increase by .52 standard deviations. The total variance explained by this model was 32.5% which was found to be significant (*F*(5,90)=8.67, p=.000).

Table 8. Independent linear models of individual illness perceptions as predictors of distress

	b	SE B	β	p
IP1 (consequences)	0.95	0.17	.52	p=.000
	R^2=.325, ΔR^2=.288, *F*(5,90)=8.67, p=.000			
IP2 (timeline)	0.39	0.22	.19	p=.076
	R^2=.136, ΔR^2=.087, *F*(5,89)=2.79, p=.022			
IP3 (control)	0.41	0.22	.20	p=.070
	R^2=.127, ΔR^2=.078, *F*(5,89)=2.60, p=.031			
IP4 (tx control)	0.48	0.26	.18	p=.084
	R^2=.123, ΔR^2=.075, *F*(5,90)=2.53, p=.034			
IP6 (coherence)	0.18	0.23	.09	p=.432
	R^2=.100, ΔR^2=.050, *F*(5,90)=1.99, p=.087			

B = Beta; β = Standardised Beta

3.5 Recruitment and Retention

3.5.1 Rates of participation

In order to answer the feasibility question regarding recruitment and retention rates, a recruitment flow-chart was developed (see Figure 6).

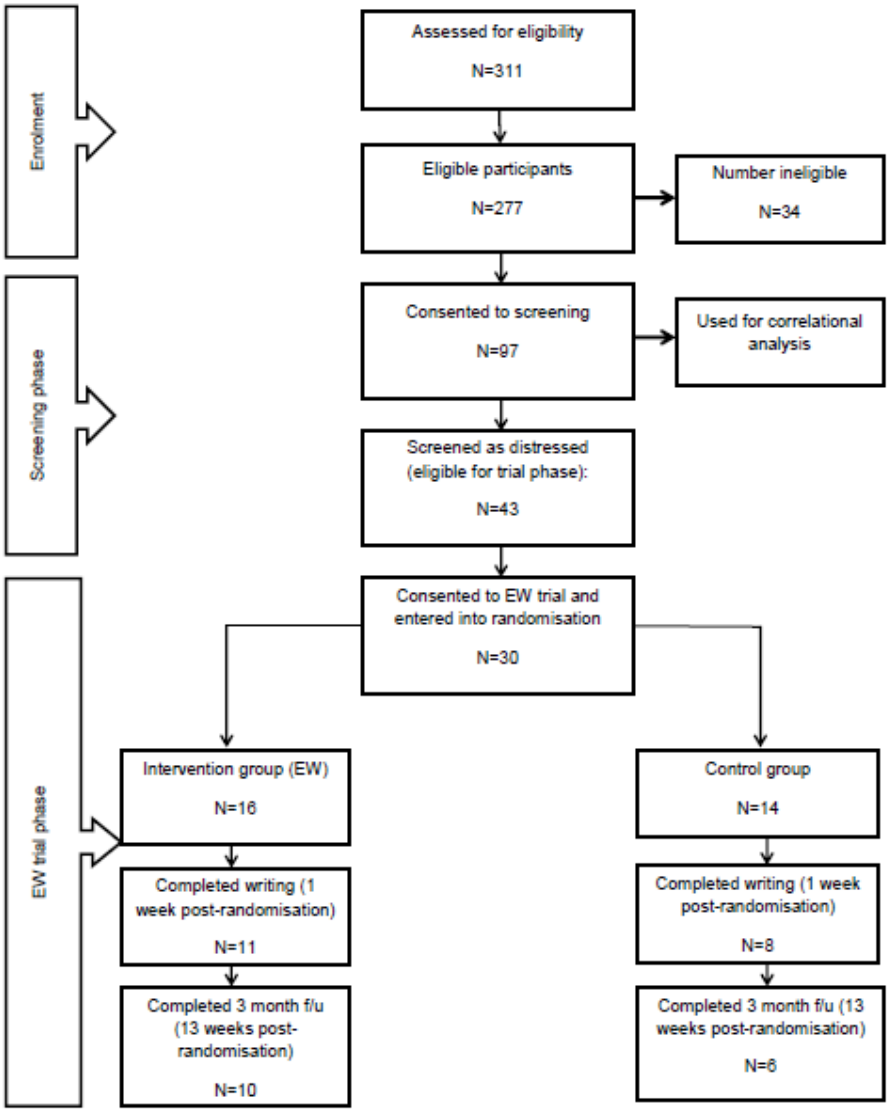


Figure 6. Recruitment flowchart

The total number of potential participants at the time of recruitment (or consort figure) was 311. This consisted of patients dialysing across four different units run by Guys and St Thomas' NHS Trust. The groups of patients at each unit is split by dialysis schedule; approximately half dialyse on a Monday, Wednesday and Friday and half dialyse on a Tuesday, Thursday and Saturday. These groups are further split into three shifts; those that dialyse in the morning, in the afternoon, and in the evening (known as the 'twilight' shift). All patient groups at these four units were screened for eligibility, apart from those on twilight shifts, and those dialysing on a

Tuesday, Thursday and Saturday afternoon at Tunbridge Wells unit (these groups were not screened due to time limitations).

Of the total number of potential participants, approximately 277 (89%) met eligibility criteria for screening and of these, 97 (35%) consented to the distress screening phase of the study and thus completed the baseline questionnaires. A total of 43 (44%) of these patients met the cut-off for distress on the GHQ-12 and were therefore deemed eligible for the trial phase. Of these, 30 (70%) agreed to complete the writing task. Reasons for not wanting to complete the writing task included; it being too difficult to write whilst dialysing, lack of confidence in writing ability and not being well enough to write. Out of the 30 who agreed to write, 16 were randomised into the EW condition and 14 into the control condition. Within the EW condition, 5 patients discontinued the intervention (1 moved to a different ward, 2 declined without giving reason, 1 found writing too stressful whilst dialysing and 1 found the writing too upsetting). Within the control condition, 6 patients discontinued the intervention (3 declined without giving a reason, 2 found it too difficult, and 1 went into hospital). In the EW condition, 1 was lost to follow-up (they were recruited too late in order to collect follow-up data prior to analysis) and in the control condition, 2 were lost to follow-up (one died and one went into hospital). Therefore, the attrition rate for the trial phase of the study was 19/43 or 44.2%.

3.5.2 Differences between participant groups

Table 9 below displays differences in demographic and clinical data between those that completed the baseline screening phase, those who were eligible for the EW trial phase, those who consented to the EW trial phase, those who completed all three writing sessions and those who failed to complete all three writing sessions.

Table 9. Demographic and clinical data for screening and trial phase participants

Variable	Sample consenting to screening phase	Participants eligible for EW trial	Participants consenting to EW trial	Completed writing? Y	N
Gender (male/female)	51/46	20/23	13/17	8/11	4/6
Age (mean years)	62.4	59.8	60.3	61.3	57.3
Dialysis vintage (mean)	5.8	6.09	6.33	4.1	9.0
Mean GHQ-12 score	13.3	18.55	19.14	18.5	20.5

As the table shows, there does not appear to be any important differences in gender or age between the different groups of participants. GHQ-12 scores are higher for participants eligible for the EW trial by design (only patients who scored as clinically distressed were eligible). The mean dialysis vintage does not appear to differ for the first three groups but is quite different when comparing those who successfully and unsuccessfully completed the writing task (those who were successful appear to have spent a lower number of years on dialysis than those who were unsuccessful). The result of a t-test comparing these two groups was not significant ($t(27)=2.01$, $p=.054$), although a large effect size was calculated ($d=0.68$).

3.6 Acceptability and Safety

Acceptability was described based on treatment fidelity and patient evaluation data.

To determine fidelity, an experimental manipulation check was carried out. This involved requesting an independent rater not involved in the study and blinded to condition membership to judge whether each participant was randomized to either the EW or neutral writing condition, by reading through each writing script (i.e., were they writing about thoughts and feelings or about facts?). The answers were then cross-checked with actual treatment allocation. Table 10 shows the results.

Table 10. Table displaying results of fidelity check

Patient identifier	Actual treatment allocation	Independent rater: EW or Neutral?
M03	EW	EW
M05	EW	EW
T11	Neutral	Neutral
T12	EW	EW
T13	Neutral	EW
T16	EW	EW
T17	Neutral	Neutral
J09	EW	EW
J14	Neutral	Neutral
J17	Neutral	Neutral
J20	Neutral	Neutral
J23	EW	EW
J32	EW	EW
J46	Neutral	Neutral
J47	Neutral	Neutral
J50	EW	EW
J58	EW	EW
J72	EW	EW
J73	EW	EW

According to the table, the independent rater correctly judged 18/19 conditions correctly. This meant a fidelity accuracy rate of 95%.

Those who successfully completed the writing task mostly gave positive feedback, reporting that they found it beneficial. Qualitative data was gained informally by simply asking participants how they had found the EW task following their final session. Some of the positive qualitative responses included:

“Yes, I liked it; it was helpful to get my thoughts on the page”.

“It was something to do to fill the time”.

“I was surprised by how much anger it brought out, I can see why it is helpful”.

“Yes, I found it somewhat helpful, I enjoy writing anyway”.

Some of the less positive comments included:

“I did not find it particularly helpful since my problems are not connected to dialysis but to other things happening in my life”.

"I found it difficult to do on one of the days because I had a fistula put in my writing arm".

"I am not sure what I have written about is the 'right' thing".

One participant who was randomised into the control condition commented "I was surprised that the instructions did not ask me to write about feelings since it is the feelings evoked by medications that are important". In addition, another participant commented that it would be easier to complete the writing at home and said "I get too distracted when I'm in the ward. At home I can think more easily and concentrate". Finally, as previously mentioned, a small number of participants who initially consented to the EW trial, failed to complete the writing task. Most of the reasons for this related to the writing being too physically demanding whilst on dialysis (they were either too unwell or felt too tired).

Safety of the procedure was determined based on whether there were any reports of increased distress or other problems, as a result of the intervention. In order to examine whether there was a short-term increase in distress, an ANCOVA was completed to compare the depression (PHQ-2) scores for the two groups at one-week post-intervention. According to the ANCOVA result, there was no significant effect of condition on depression scores at one week follow-up, when controlling for baseline depression scores, $F(1,16)=1.90$, $p=.187$, partial $\eta^2=.11$. The mean depression score for the EW group was 2.45 (SD=2.11) and was objectively higher than the score for the control group, which was 1.12 (SD=1.89), at one week, although scores for both groups had decreased since baseline (see Table 9). One lady reported that she found the writing too upsetting and therefore no longer wanted to continue. Her heightened distress was highlighted to the medical care team.

3.7 Preliminary Outcomes

3.7.1 Differences at follow-up

Preliminary outcome data were derived from the GHQ-12, as well as the measures of self-reported symptoms, illness perceptions and clinical health markers, to explore the potential clinical efficacy of the EW procedure. Ideally, a multi-level model would have been computed to quantify significant changes at follow-up, thus determining efficacy of the intervention. This would have consisted of evaluating the changes in effects between groups with respect to mean values at each assessment (baseline and 3 months) and within the same group over time with a

repeated-measurement analysis of variance, using a mixed-effect modeling procedure. However, the final sample size was too small to be able to power robust statistical analysis. Therefore, differences in mean scores between groups at 3 months were measured using independent sample t-tests and effect sizes were calculated. Table 11 below displays the results

Table 11. Differences between groups at 3-month follow-up (means, standard deviations, 95% confidence intervals, results of independent samples t-test and Cohen's d effect size)

Variable Mean (SD) [95% CI]	3-month follow-up EW	Neutral	T-test result	Effect size (Cohen's d)
Primary Variable				
GHQ-12 score	16.20(7.06) [12.33, 20.78]	17.67 (5.82) [12.60, 22.50]	t(14)=-0.43, p=.676	d=0.23
Secondary Variables				
BIPQ score	27.60 (5.52) [24.38, 31.17]	31.00 (5.10) [27.00, 34.67]	t(14)=-0.23, p=.241	d=0.63
VAS-Pain (at rest) score	3.20 (2.97) [2.75, 7.00]	4.67 (2.73) [1.80, 5.00]	t(14)=-0.98, p=.342	d=0.52
CFQ score	5.80 (3.68) [3.67, 8.08]	4.33 (3.88) [1.40, 7.67]	t(14)=0.76, p=.461	d=0.39
PHQ-2 score	3.40 (2.80) [1.80, 5.00]	3.50 (2.60) [1.60, 5.50]	t(14)=-0.72, p=.944	d=0.04
SBP mmHg	142.20 (29.82) [124.0, 160.27]	159.67 (17.73) [148.17, 177.60]	t(14)=-1.29, p= .217	d=0.71
DBP mmHg	76.10 (16.29) [66.00, 85.44]	77.67 (7.39) [71.33, 84.0]	t(14)=-0.22, p=.829	d=0.12

SBP, Systolic blood pressure; DBP, diastolic blood pressure

As the above table shows, none of the variables showed statistically significant differences between the group conditions at 3 month follow-up. However, the t-test results represent some important effect sizes. There was a small effect size for group differences in distress, with the EW group having lower scores at 3 months. There was also a small-medium effect size for differences in fatigue, and a medium effect size for pain, with both scores being lower in the EW group. There was a medium–large effect size for illness perceptions, with a lower (and therefore more positive) score in the EW group, and finally, a medium-large effect size for systolic blood pressure, with lower scores in the EW group.

Finally, two simple linear regressions were carried out to determine whether group condition could predict distress levels or illness perception scores at 3 months, when controlling for baseline GHQ-12 and BIPQ scores respectively. The results are shown in Table 12 and Table 13.

Table 12. Linear model of group condition as predictor of distress at 3-months (controlling for baseline GHQ-12 scores), with 95% confidence intervals reported in parentheses

	b	SE B	β	p
Constant	6.58 (-5.39, 18.54)	5.54		p=.256
Group condition	-1.74 (-8.30, 4.82)	3.04	-.14	p=.576
Baseline GHQ-12 score	0.59 (0.02, 1.16)	0.27	.52	p=.045

R^2=.533, ΔR^2=.284, $F(2,13)$=2.58, p=.114

The total variance explained by the above model was 53% which, overall was not found to be significant $F(2,13)$=2.58, p=.114. Baseline GHQ-12 score was a better predictor of GHQ-12 score at follow-up than group condition, although it did not have a significant predictive value. For group condition, the beta values indicate that the GHQ-12 scores at 3 months were -.14 standard deviations lower in the EW group than the control group, but this difference was not statistically significant.

Table 13. Linear model of group condition as predictor of illness perceptions at 3-months (controlling for baseline BIPQ scores), with 95% confidence intervals reported in parentheses

	b	SE B	β	p
Constant	18.54 8.06, 29.04)	4.85		p=.002
Group condition	-2.63 (-0.84, 6.62)	2.30	-.24	p=.275
Baseline BIPQ Score	0.50 (0.12, 0.85)	0.18	.58	p=.016

R^2=.656, ΔR^2=.343, $F(2,13)$=4.92, p=.026

The total variance explained by the above model was 65% which, overall was found to be significant $F(2,13)$=4.92, p=.026. Baseline BIPQ score was a significant predictor of illness perceptions at follow-up (b=0.50, β=.58, p=.016), with the results indicating that as the baseline BIPQ score increased by one standard deviation, BIPQ score at 3-months increased by .58 standard deviations. For group condition,

the beta values indicate that the BIPQ scores at 3 months were -.24 standard deviations lower (and therefore more positive) in the EW group than the control group, but this difference was not statistically significant.

3.7.2 Randomisation

Despite the small numbers, it was thought pragmatic to complete a randomisation check to determine whether the two group conditions were significantly different at baseline or not. Table 14 below shows the results from comparing the two randomisation conditions across important demographic (gender and age), clinical (dialysis vintage and co-morbidity), and psychological (depression and distress) variables, symptoms (fatigue and pain), and illness perceptions. Depending on the type of variable, the table displays differences in numbers, means and standard deviations, and the corresponding effect sizes.

Table 14. Differences between randomisation conditions (EW and Neutral writing) at baseline

Variable	EW group (n=16)	Neutral writing group (n=14)	T-test or chi-square result	Effect size (OR or Cohen's d)
Gender (n) (male/female)	9/7	8/6	$\chi^2(1)=0.00$, p=.626	OR = 0.96
Mean age (SD)	57.88 (15.62)	63.00 (14.6)	t(28)=-0.92, p=.364	d=0.34
Mean Dialysis Vintage (SD)	6.38 (8.13)	6.29 (5.99)	t(28)=0.03, p=.973	d=0.01
Co-morbidity (n) (None/Medium/High)	1/11/4	3/9/2	$\chi^2(2)=1.74$, p=.419	N/A
SBP	134.00 (20.91)	138.79 (24.67)	t(28)=-0.58, p=.570	d=0.20
DBP	75.81 (11.40)	75.64 (16.09)	t(28)=0.03, p=.973	d=0.00
Mean GHQ-12 score (SD)	19.69 (5.74)	18.46 (6.25)	t(27)=0.55, p=.587	d=0.20
Mean BIPQ score (SD)	41.87 (8.06)	38.93 (10.26)	t(28)=0.25, p=.806	d=0.31
Mean CFQ score (SD)	7.38 (2.25)	7.14 (2.88)	t(28)=0.25, p=.806	d=0.09
Mean VAS-Pain (at rest) score (SD)	5.38 (3.48)	4.14 (3.18)	t(28)=1.07, p=.323	d=0.37
Mean PHQ-2 score (SD)	3.00 (2.03)	2.14 (1.83)	t(28)=1.21, p=.238	d=0.44

OR, Odds Ratio; SBP, Systolic blood pressure; DBP, diastolic blood pressure; N/A, not applicable.

As the table shows, the two group conditions did not significantly differ on gender, age, dialysis vintage, co-morbidity, blood pressure, illness perception score, fatigue, pain, depression or distress (all $p>0.05$, odds ratio=0.96). However, the Cohen's d calculations indicate that there were small-medium sized effects for differences in age, distress, illness perceptions, pain at rest and depression.

4.0 DISCUSSION

This study consisted of two phases in order to answer different research questions, with different corresponding designs. The first phase used a cross-sectional, questionnaire design with the aim of establishing which factors were associated with heightened distress. The second phase used a two-armed randomised-controlled trial design with one follow-up time point. This phase aimed to establish the practicality of using an EW intervention with dialysis patients, and whether it had any effect on any variables at follow-up, thereby establishing its potential clinical efficacy. No previous research has examined the correlates of distress using the GHQ-12 measure with dialysis patients. Furthermore, this is the first study to investigate using EW as an intervention with this particular health population.

This section will discuss the findings of the study, firstly by referring to the characteristics of the sample, and then in relation to the research questions set out in the introduction. Attention will be drawn to the limitations of the study and recommendations for future research.

4.1 Findings

4.1.1 Sample characteristics

The study sample was split equally by gender and encompassed a wide range of ages (26 to 87), with a median age of 68. The median age of prevalent patients in the UK on HD is currently 66 years (UK Renal Association, 2013). Therefore, in terms of demographics, the sample can be considered representative of the general dialysis population. A relatively small proportion of the sample was in employment (13.4%) and a third of the sample was unable to work due to their health. This fits with existing studies, which have highlighted the difficulties for dialysis patients to remain in work after beginning treatment (e.g., van Manen et al, 2001). A relatively large proportion of the sample was retired (46.4%), which makes sense considering the average age demographic.

The average length of time on dialysis for this sample was approximately 6 years and the majority also suffered from at least one other co-morbid condition. Considering the substantial length of time on dialysis and high level of co-morbidity, it is not surprising that a large number of patients were suffering from significant levels of fatigue (62%). This result is similar to other studies which have recognised that fatigue is one of the most frequent symptoms for dialysis patients (e.g., Jhamb, Weisbord, Steele & Unruh, 2008). However, the average recorded values for pain

were 3.2 and 3.9 out of a possible 10, which is not as high as other researchers have suggested (e.g., Gamondi et al, 2013). Overall, fatigue seemed the more common and more burdensome symptom for this sample.

Consistent with previous studies in dialysis patients (e.g., Weisbord et al, 2005), the results showed that a sizable proportion of the sample was experiencing high levels of psychological distress, with 44.3% meeting the clinical cut-off on the GHQ-12. In addition, 24% of the sample met the clinical cut-off for depression on the PHQ-2, which fits with recent study findings that have estimated the prevalence of depression to be between 20 and 30% (Wilson et al, 2006; Martin et al, 2004). The discrepancy between the number of 'depressed' and the number of 'distressed' patients supports the idea that dialysis patients are experiencing a myriad of psychologically relevant problems, above and beyond diagnosable 'depressive symptoms' and therefore supports the use of a more generalised measure, such as the GHQ-12, to capture this spectrum of problems.

In terms of illness perceptions, the most negatively rated item was the one assessing timeline. In other words, within this sample, patients were likely to perceive that their kidney problem would continue for a long time. The fact that patients were likely to hold this belief is understandable, since kidney disease is a chronic condition, a fact that would have been made clear to them upon diagnosis. As outlined in the introduction, previous studies have shown timeline beliefs to be particularly important for dialysis patients as they can influence adherence to self-care behaviour (e.g., Chilcot et al, 2010). Within this study sample, perceptions of treatment control were rated more positively than the other illness perceptions assessed. This may have been due to the fact that, in order for patients to cope with the reality of dialysis treatment and feel able to dedicate so much of their daily lives towards it, they have to believe that the treatment is ultimately helpful and capable of keeping them alive. Furthermore, patients completed the questionnaires whilst treatment was concurrently taking place, which may have increased its salience and prompted respondents to rate this item more positively. Whatever the reason, it is encouraging to know that this group of patients perceived dialysis treatment to be beneficial overall. Illness coherence was also rated relatively positively, meaning that these patients believed they had a good understanding of their kidney problem, which is also encouraging.

4.1.2 What factors are associated with distress?

The first aim of the study sought to establish which factors are associated with psychological distress for dialysis patients. The results from the first phase showed that distress was significantly associated with the self-reported symptom variables (fatigue and pain), illness perceptions, depression and age, but with none of the clinical variables. These relationships will be discussed in further detail below.

There was a significant relationship found between depression and distress, which is unsurprising. Most research on psychological factors in HD patients has focussed on measuring symptoms of depression and anxiety, rather than general distress. For the purposes of this study, distress was chosen as the main dependent variable because it was thought to be more clinically relevant for this patient group. The finding is enlightening since, unlike similar existing findings, it is not contaminated by the overlap between the somatic symptoms of depression and the physical symptoms of renal failure and side effects of treatment. It therefore highlights the usefulness of using a more general measure of distress, such as the GHQ-12, for this population.

Another significant relationship was discovered between distress and fatigue. The higher a patients fatigue, the more distressed they were, which supports the hypothesis. As previously discussed, fatigue is a common complaint for patients undergoing dialysis treatment and could therefore explain its strong correlation with distress. In addition, the CFQ measure is sensitive to mental fatigue (Cella & Chalder, 2010) which has shown an association with emotional distress in other chronic illnesses, such as heart failure (Falk, Patel, Swedberg & Ekman, 2009). Previous research has indicated that there are a number of physiological, behavioural, treatment-related and individual characteristics which may correlate with fatigue and that it is related to impaired QOL (Jhamb et al, 2008). Some of the physiological causes are thought to include anemia, malnutirition, uremia, dialysis inadequacy, hyperparathyroidism, coexisting chronic illness, sleep disorders, depression and side effects of medication. Fatigue and depression are also closely interrelated, for example Liu (2006) found that fatigue scores were significantly higher for those HD patients who were depressed than for those who were not depressed, and that depression was a significant predictor of fatigue. Some researchers have postulated that depression may contribute to fatigue through inflammatory pathways (e.g., Lee et al, 2004).

Illness perceptions were also found to significantly correlate with distress. As predicted, the more negatively patients rated their illness perceptions, the more distressed they were. This has face validity since the concept of 'illness perceptions' relates to how patients think about their illness and refers to patients' interpretation of how their illness affects them; how long their illness will last; how much control they have over it; how much they understand it and, how much it affects them emotionally. Research on illness perceptions in HD patients is gaining momentum and this result replicates those of previous studies which have demonstrated a relationship between illness perceptions and psychosocial outcomes. For example, Chilcot et al (2011b) found that the addition of illness perceptions explained a further 24.3% of variance in depression scores, over and above demographic and clinical factors. Timmers et al (2008) also found that illness perceptions significantly explained the variance in HRQOL scores in dialysis patients (as measured by the Short Form Health Survey) and a group of studies have shown that the perception of the burden of illness is associated with general well-being, happiness and depression (Kimmel, 2000).

The second regression model revealed that the specific perception of illness consequences was a significant independent predictor of distress, implying patient distress is strongly related to how negatively patients view the effects of their illness. This adds to previous research on illness perceptions in dialysis patients which has found perceived consequences to be an important determinant of depression (Chilcot et al, 2011b; Griva et al, 2010). Interestingly, in this case, perceived control did not have a significant impact on distress scores. This is in contrast to existing literature which has shown control beliefs to be highly related to emotional distress (Christensen and Ehlers, 2002). Christensen, Turner, Smith, Holman and Gregory (1991) speculate that patients' control appraisals depend on the degree to which they are congruent with contextual or situational factors. In this study, it may have been that patients held strong beliefs in the health-providers ability to control outcomes, which meant their perceptions of personal control were relatively neutral and therefore did not impact on their distress.

In addition, pain (both rates of pain intensity and unpleasantness) was found to significantly correlate with distress. Again, the direction of the hypothesis was confirmed; the higher patients rated their pain and the more unpleasant their experience of it, the more distressed they were. This finding is in agreement with existing evidence suggesting a relationship between pain and depression (e.g., Binik et al, 1982) and QOL (Shayamsunder et al, 2005). One study found that

chronic pain experienced by ESRD patients was associated with a two-fold increase in depression (Davison & Jhangri, 2005).

The results of the regressional analysis showed that symptom variables and illness perceptions explained an extra 35% of the variance in levels of distress, over and above gender, age and levels of co-morbidity. Demographics and co-morbidity only accounted for small proportion of the variance (10.5%). Of these variables, fatigue was the strongest predictor, followed by illness perceptions. This indicates that patients' levels of fatigue and illness beliefs are crucial when assessing distress in this population. This finding supplements existing research which has established the importance of psychosocial factors in determining outcomes in dialysis patients. For example, Vasquez et al (2005) found that anxiety and depressive symptoms explained additional variance in HRQOL above that accounted for by demographic and clinical factors. In addition, a meta-analysis by Chan et al (2012) showed that the association between psychosocial factors and QOL had a medium effect size of 0.38.

Finally, distress significantly correlated with age in that, the older the patients were, the more likely they were to be distressed. This result was not hypothesised but is interesting to consider. The fact that distress and depression is higher in older dialysis patients has been reported in a number of studies (e.g., Theofilou, 2011; Iacovides et al, 2002). It is possible this is due to the decline in physical health with age, an effect which is exaggerated in patients with a chronic illness.

The fact that distress was not associated with any of the clinical variables, underscores the relative importance of self-reported symptoms and illness beliefs in determining levels of distress. In addition, there were no significant differences across other demographic or lifestyle factors but small effect sizes were found for gender (men were slightly more distressed that women).The lack of effect found for gender contradicts studies which have shown female patients to have higher distress scores than males (e.g., Theofilou, 2011). Previous research has also shown that being married is related to better emotional health (Chiang et al, 2005), which was thus not supported by this study's results. There were also no statistically significant differences when comparing distress levels between those with high and low levels of inflammation (as measured by CRP), although a small effect size was detected (those more inflamed were slightly more distressed). This is interesting considering the research linking depression with inflammation in renal patients (e.g., Bossola et al, 2010) and suggests that a significant difference may be revealed with

a larger sample. It is also possible that a stronger effect size would have resulted if depression was examined as the main dependent variable, or if a more sensitive measure of depression were used, such as the PHQ-9 or BDI. In this study sample, distress levels were unrelated to years on dialysis or co-morbidity. This is in contrast to previous results which have indicated that depression is associated with these factors (Hedayati et al, 2008). However, Chilcot et al (2011a) also found that there was no evidence of an association between depression and co-morbidity.

4.1.3 Feasibility of EW: recruitment and retention rates, acceptability and safety

Since recruiting and retaining participants is crucial for any research design intended to document evidence-based treatment, the second aim of the study sought to determine whether the EW intervention was feasible with regards to recruitment and retention rates. About a third (35%) of those patients screened as eligible agreed to take part in the first phase of the study. Of the 43 who met inclusion criteria, 30 agreed to take part in the second phase, which involved trialling the EW intervention. This meant the recruitment rate for the intervention phase was 70%. However, only 16 participants (37%) completed all three writing sessions, as well as baseline and 3 month follow-up measures. Participation rates for previous trials of EW with other chronic health populations have varied. In a study aiming to implement EW in a cancer clinic, Morgan et al (2008) achieved a participation rate of 72%, but in Halpert, Rybin and Doros' study (2010) of EW with IBS patients, only 53% complete all four days of writing, and in Broderick et al's study (2004), 49% completed the full protocol. Broderick et al argued that this percentage was an accurate reflection of the degree to which patients adhere to self-administered interventions in the community. Looking further afield, some studies investigating alternative low intensity interventions for chronic health populations have recorded retention rates of less than 50%. For example, the retention rate was 40% for a brief psychological intervention for families with children newly diagnosed with cancer (Kazak et al, 2005) and in a pilot study of online breast cancer support; only 49% of those expressing an interest in the study, provided informed consent to enrol. Therefore, in relation to other trials of similar interventions, our participation rate seems comparatively high, whereas the retention rate is comparatively low. This suggests that, for those patients who are dialysing and who are clinically distressed, EW presents an interesting and viable method of self-guided support. However, the retention rate within this study was relatively low due to the percentage of participants who were unsuccessful in completing all three writing sessions since

they found it overly stressful or upsetting. Overall, this indicates that, although dialysis patients may endorse the idea of EW and can feasibly write whilst dialysing, there are a number of implementation issues relating to the practicality and process of writing, which represent significant challenges. Many of the participants commented that they would be willing to complete the writing sessions at home, in their own time. Some also commented that they would be happy to talk about their kidney problem, and would prefer this to written disclosure. Previous studies have suggested a number of methods that could be used to overcome the implementation issues and improve adherence rates (see section 4.3 below).

No statistically significant differences were detected between the groups of patients at different stages of the study (those eligible for the trial phase, those that consented to take part and those who successfully and unsuccessfully completed the writing sessions). However, there was a minor difference between those who completed the intervention; those who were successful had experienced a lower number of years on dialysis on average than those who were unsuccessful. This information could be used to identify those more likely to complete the study and therefore benefit from it. If this difference were detected with a larger sample, the intervention may need to be tailored to target those with a shorter dialysis vintage. Kimmel (1990) proposes that the course of HD can be understood as being composed of several stages of varying lengths (e.g., initial treatment, maturity phase and final phase of death and dying) and that different challenges are posed by each of these stages. It may be the case that the EW intervention is most beneficial for those who are in the period of 'initial treatment' since at this time, patients are undergoing a considerable amount of adjustment, and could therefore represent the time that patients' views of their illness are most amenable to change.

When considering fidelity, the experimental manipulation check confirmed that the independent rater could correctly identify the conditions for 18 of 19 writing scripts (95%), which means that the different instructions produced different therapeutic experiences and that they were clear enough for patients to adhere to them fittingly. In terms of the safety of the intervention, the results indicated that there was no short-term increase in distress (as measured by the PHQ-2 at one week follow-up) following the intervention, and there was only one anecdotal report from a researcher regarding a single patient who became distressed, following their first writing session. This reaction was realised upon collection of their second writing script and relayed to the appropriate staff on the renal team, prior to the patients' withdrawal from the study. No other patients who completed the writing became

significantly distressed. This is reassuring as it suggests this type of intervention can be safely applied in a renal clinic setting, despite studies suggesting that people can feel more distressed in the hours immediately after writing (Pennebaker & Seagal, 1999).

4.1.4 Feasibility of EW: preliminary outcomes

Finally, the study sought to verify preliminary outcomes and therefore the potential clinical efficacy of using EW for those on dialysis. To ensure group equality, a randomisation check was performed. The two groups did not differ significantly across any of the demographic, clinical, psychological and symptom variables. Although, according to the effect sizes, there were small differences in terms of age, blood pressure, distress, illness perceptions and medium differences in depression. This may have impacted on differences in the outcomes at 3 month follow-up. Analysis of a larger trial sample would determine if this were the case.

Results from the trial phase showed that there were no statistically significant differences between the groups on self-reported symptoms, illness perceptions or clinical outcome variables. It is possible that this was largely due to the size of the sample, which meant there was limited power to determine significant variances. However, the effect sizes did provide some useful and clinically meaningful results. There were at least small effect sizes detected for differences in distress, fatigue, pain and illness perceptions at 3 months.

In terms of the primary outcome variable of psychological distress, there was a small-sized effect for differences between scores at the 3 month end point (d=0.23), which is larger than the modest effect size found by Frattaroli (2006, d=0.15). The distress levels were also lower in the EW group than the control group at follow-up. This difference is in-line with the original hypothesis and indicates that the intervention had some positive effect on distress levels, supporting previous findings that have shown a similar effect on emotional well-being for other medical populations (e.g., Gellaitry et al, 2010).

With regards to the additional variables, although there was an effect for fatigue score, it was relatively small (d=0.39). This may signify the fact the fatigue is an enduring problem for patients on dialysis and is perhaps more directly linked to clinical health markers, and therefore not so amenable to change. There was a medium effect size for the difference in the two group's pain at rest scores (d=0.52) and the pain scores were lower in the EW group. A medium-large sized effect was

detected for differences in illness perceptions (d=0.63). Overall, these findings suggest the EW intervention had positive effects for levels of fatigue and pain, in line with previous studies that have suggested benefits of symptom reduction may be gained through used of this technique for with people with medical conditions, such as fibromyalgia (Broderick et al, 2005).

In terms of physiological outcomes, there was also a medium-large effect size detected for differences in systolic blood pressure (d=0.71) with these values being lower in the EW group. Therefore, the EW intervention also had some important beneficial effects on the clinical outcome of blood pressure. This result is consistent with individual studies and reviews which have indicated the effectiveness of EW on physiological outcomes (e.g., Frisina et al, 2004). For example, Pennebaker, Hughes and O'Heeron (1987) found systolic blood pressure and heart rate dropped to levels below baseline following the disclosure of traumatic topics, but not superficial topics. In addition, McGuire et al (2005) found that elevated blood pressure significantly decreased over time, following emotional disclosure, (d=0.36 for SBP and d=0.21 for DB, although they found no effect of group condition. Despite this study's result, it is important to consider the fact that in this study, blood pressure was not recorded in a systematic way; the most recent blood pressure recorded by the renal team was used, which was not always on the same day as follow-up took place.

The first of the two final regression outputs show that group condition and baseline distress levels did not significantly predict distress levels at follow-up. Despite this, distress levels were objectively lower for both groups at 3 months, than they were at baseline. The second output indicated that baseline illness perceptions significantly predicted illness perceptions at 3 months, but showed no group effect. Similarly, there was an objective difference between the two group scores (perceptions were more positive in the EW group) and scores had decreased for both groups, since baseline. There was a larger effect size for difference in illness perceptions (d=0.63) than distress (d=0.23) which seems to suggest the writing had a bigger impact on patients' beliefs about their illness, than their distress. This could indicate that EW helps patients to modify illness/treatment specific distress, since patients were encouraged to write about their treatment, but that this change does not translate to their general distress levels (at least within this follow-up time period). This could be because 'distress' is also related to non-illness-related factors, such as personal or social issues. Replication of this finding with a larger sample and with a longer follow-up would be needed to confirm the nature of this time-group interaction.

4.2 Implications for Theory

Although the current study did not directly test a specific theory or model of EW, the findings do have some implications for the theory underlying the relationship between illness perceptions and distress, and for the theoretical mechanisms underpinning the intervention.

The current findings lend support to the strength and usefulness of the Common Sense Model of Self-Regulation (Leventhal et al, 1997), which suggests illness perceptions inform and direct coping behaviour. Hagger and Orbell's (2003) meta-analysis showed that when patients have more positive beliefs in controllability and curability of illness, it positively influences their well-being. Evidence to support this model co-exists with a number of studies of ESRD patients which have shown illness perceptions are predictive of health-related outcomes, including survival (Chilcot et al, 2011a; Van Dijk et al, 2013) and non-adherence (O'Connor et al, 2008; Chilcot et al, 2010). Theoretically, maladaptive illness beliefs are likely to be associated with poor coping behaviour, which could impact on ability to manage physical health and ultimately, survival. Longitudinal studies looking at the pattern of illness perceptions and health outcomes over time, in chronic illness, has mostly been a recent development. For example, Dempster et al (2010) found that oesophageal cancer sufferers, whose personal and treatment control beliefs decreased over time, were more likely to become anxious and depressed. Further research is necessary to understand how exactly illness perceptions influence coping behaviour for dialysis patients, and what factors mediate the relationship between them.

This study provided the important finding that perceived consequences independently predicted distress. Prior to the development of 'illness perceptions' as an idea, a group of studies by Devins and colleagues studied the idea of 'illness intrusiveness' in ESRD patients. This was defined as "illness induced disruptions to valued activities and interests that limit the availability of personally rewarding experience and compromise quality of life" (Devins et al, 1983). Conceptually, this appears similar to the more modern construct of 'illness consequences'. Their findings supported the claim that patients' perceptions of increased intrusiveness were associated with distress. They also found that the relationship was moderated by identity and hypothesised that patients whose self-definitions are strongly tied to their illness role, may perceive fewer potential rewarding non-illness experiences and therefore experience greater emotional distress (Devins et al, 1997). It is

possible that this was also true of the relationship found in this study, but it cannot be verified since the perception of illness identity was not measured.

The fact that distress was strongly related to self-reported pain and fatigue, as well as illness perceptions, is also of theoretical interest. According to the CSM model, pain and fatigue can be viewed as symptoms within the perception of illness 'identity', and therefore as directly related to the cognitive representation of illness. Results of this study lend support to this theory which implies that subjective appraisal of these factors effects the outcome of psychological distress. Pain and fatigue are both considered multidimensional concepts made up of physical, social and psychological components (e.g., Davison & Jhangri, 2005; Jhamb et al, 2008) and have both shown relationships with illness perceptions (Alsen, Brink, Persson, Brändström, & Karlson, 2010; Foster et al, 2008). However, patient ratings of fatigue and pain could be unrelated to dialysis treatment and thus viewed as independent health-related outcomes (as they were in the second phase of the study). More research is required to disentangle the relationship between each construct, but the fact that all three seem to share a common cognitive component, indicates an area of potential change to be targeted.

In this study, EW was the chosen intervention to implement change. The observed differences between the randomisation groups at follow-up suggest something about the EW procedure was more effective than writing about emotionally neutral topics. The differences appear to support Pennebakers' original theoretical model and results of other studies which suggest the effects vary as a function of experimental parameters and fits with the idea that it is the formation of a narrative which is important. However, other studies have concluded contradictory outcomes, for example Craft, Davis & Paulson (2013) found EW had an improvement overall but found no difference between groups. The precise mechanism by which writing confers health benefits remains unclear. It is possible EW works by re-framing memories and thoughts, similar to cognitive reappraisal in CBT (Pennebaker et al, 1990). The fact that this study showed a medium sized effect for differences in illness perceptions at follow-up indicates that the modification of cognitive illness appraisals may be a contributory factor. Formal linguistic analysis would be required to discover whether there are objective differences in language (see section on future research). The fact that EW had an effect on blood pressure also supports the theory that unexpressed emotion can affect physical health by raising the sympathetic nervous system and that, by default, expressing emotion can lead to lowering of blood pressure (Mauss & Gross, 2004). Overall, the finding that EW had

a relatively stronger effect on blood pressure than distress fits with the opinion that self-report outcomes generally do not bring about as significant findings as objective health outcomes (Pennebaker & Chung, 2011).

It has been proposed that the reason no single theoretical perspective has yet explained effects of EW could be because it affects people on number of different levels. In other words, the effect sizes are small due to moderators, such as demographics or social environments (Lu & Stanton, 2010). The current study results indicate that those with a shorter dialysis vintage were more likely to complete the intervention, suggesting it may be more useful for those who are in the initial stages of adjustment. Furthermore, this would suggest a potential need to provide booster sessions to respond to changes in situation and emotions confronted at different stages of the illness. There is some evidence that benefits are larger for men (Smyth, 1998), for those who are ambivalent about disclosing emotions (Averill et al, 2013) and that benefits can vary according to ethnicity (Lu & Stanton, 2010). Norman et al (2004) also found higher baseline negative affect predicted improved positive affect and daily disability for chronic pelvic pain patients 2 months after disclosure writing. The wording of the instructions may have also influenced the precise psychological processes targeted, and therefore the outcomes (i.e., writing about illness rather than writing about any stressful experience or trauma). Although most recent studies have used specific instructions, Pennebaker and Chung (2011) recommend that researchers provide sufficiently open instructions to allow participants the flexibility to address any issue of importance. A larger sample size would be needed to identify moderators of the effects, and to determine individual difference variables that predict who is most likely to benefit from EW and under what conditions.

4.3 Implications for Clinical Practice

From a practical perspective, the results indicate that a large proportion of dialysis patients are clinically distressed, which needs to be addressed. Although more research is needed to examine precisely how distress is linked to outcomes, this study highlights the potential utility of measuring distress, rather than depression within the dialysis population. This echoes findings in research investigating depression versus distress in type 2 diabetes. A study by Fisher et al (2007) found that 70% of patients with type 2 diabetes who scored above cut-off on the CES-D, but were not clinically depressed, displayed significant biological and behavioural outcomes usually expected to be a function of clinical depression. The authors

discussed that items on the CES-D may have reflected symptoms of anxiety, substance use and general distress, rather than clinical levels of depression and concluded that distress is more common and more has more impact than clinical depression alone. Similarly, in this study the GHQ-12 may have identified a broader more heterogeneous range of factors related to general distress, including anxiety, as well as depressive affect.

This study demonstrated that fatigue, pain and personal beliefs about illness have a more important impact on mood, than age and disease characteristics. This is important since it could help clinicians decide where to focus interventions. CBT has shown promise for ameliorating depressive symptoms in dialysis patients (e.g., Duarte et al, 2009), and has also shown benefits of reducing pain and fatigue in other illness populations (e.g., White et al, 2011; Morley, Eccleston, & Williams, 1999). Some studies have shown also that illness perceptions can be changed and that this influences outcomes (e.g., Broadbent et al; Petrie et al, 2002). Since this study discovered that specific beliefs about consequences have the most significant impact on distress, clinical staff may wish to focus efforts on changing how much patients perceive their illness is affecting them. This may be challenging, considering the fact that treatment for ESRD represents a huge burden. Potential interventions could involve finding out exactly how the illness is affecting patients' lives and applying practical solutions, or using solution-focussed therapy to help them successfully adapt and integrate the treatment into their daily lives.

In terms of feasibility, the study's retention rates revealed that EW whilst dialysing is not entirely feasible, due to the fact that many patients were simply too distressed, or physically unwell to complete the writing task. This outcome resembles that of a feasibility trial of EW patients in palliative care which also showed limited adherence (Bruera, Willey, Cohen & Palmer, 2008). The authors suggested modifying the methods and concluded that patients may need to undergo coping skills training prior to participation, since they may have been too traumatised to cope with writing. Despite the relatively poor uptake, the current study findings indicated some potential clinical efficacy for EW by demonstrating that disclosing thoughts and feelings helps patients to feel less distressed, less pain and fatigue and lowered their blood pressure. Therefore, the EW paradigm does show promise for use with dialysis patients, with some potential modifications, since it allows a way of addressing distress using a method that is short-term. EW also requires minimal professional involvement, whilst allowing easy monitoring due to frequent contact with the medical care system. Furthermore, management of kidney failure is

extremely costly in comparison to other medical conditions (accounting for ~1-2% of the total NHS budget) and is set to rise with increasing demand (Klebe et al, 2007; Baboolal et al, 2008). Such an intervention would thus provide a useful way of managing patient distress and improving health outcomes, whilst minimising costs.

Some of the implementation issues related to the fact that patients found the procedure too difficult to adhere to in written form. One could therefore implement alternative methods of disclosure, such as a self-administered video-based delivery system, or encourage patients to discuss issues and problem either informally or in a more structured support group. Support groups have been growing in popularity for those with chronic diseases, over the past 20 years (Jacobs and Goodman, 1989). This type of intervention may help patients to acknowledge their emotions and construct a narrative, within the context of a group but would require careful setting up and facilitation by a staff member in order to ensure a narrative focus.

4.4 Limitations

There are a number of limitations which should be considered when interpreting the insights gained from this study. Firstly, the findings are susceptible to the shortcomings associated with self-report methods, for example the possibility of participants misinterpreting the question, responding in a biased manner, or making an error in transcribing his or her response (Streiner & Norman, 2008). In addition, there were a number of other drawbacks to using the specific measures chosen. Firstly, the BIPQ was used to assess illness perceptions, rather than the IPQ-R, since it is quicker and easier to administer and reduces questionnaire burden for patients. This was considered a priority when designing the study since many of the participants were elderly and/or unwell. However, the item measuring identity beliefs was omitted from the adapted BIPQ version used, and therefore not included in analysis. In addition, causal beliefs were assessed but not included in the analysis since the item necessitated an open-ended response and therefore required additional coding into appropriate response categories, for example risk factors that cannot be changed (e.g., hereditary, aging), and those that can be (e.g., diet, lack of exercise). Since the perceptions of illness identity and causes were excluded from analysis, it is impossible to say whether these influenced the findings in any way. Also, anecdotally, some of the participants commented that they found the wording of the item measuring ‘consequences’ confusing (i.e., ‘how does your kidney problem affect you currently?’). This was also an issue for the GHQ-12 measure which some participants queried regarding whether the responses should be in

relation to their dialysis treatment or kidney problem, rather than their life in general. This often required clarification and in future, instructions could be altered to be less ambiguous. Completing the questionnaires whilst dialysing may have also biased the results since dialysis is likely to have enhanced symptoms such as fatigue and pain, and possibly had an impact on distress levels and illness perceptions. It would be useful to compare the outcomes of patients completing questionnaires when on and off dialysis, in order to clarify whether this has an effect, and to see whether it should be considered a confounder.

Reliance on quantitative measures for measuring complex constructs, such as distress, can also generate some limitations. Although they are time and resource efficient, such questionnaires attempt to quantify patients' subjective experiences by imposing categories important to researchers onto participant's experiences rather than allowing them to define what is important in their own terms. They are therefore unlikely to capture the diverse aspects of patients' experiences, life situations and practical issues. Focus groups could be used as a way of gathering such information, which would complement quantitative data. These types of measures also tend to be culturally biased since many are validated using predominantly white participant samples. Furthermore, due to the lack of consensus regarding how to measure distress and depression in this particular clinical group, a wide variety of measures have been previously used, which make it difficult to place the present study findings within the context of existing literature. It is also difficult to make detailed comparisons due to overlap between different symptoms and factors. Research within this field needs to become more standardised with regards to the types of measured used. This would enable researchers to find out more about how distress (as measured by GHQ-12) impacts on health-related outcomes, and would promote a more in depth understanding of the relationship between variables, and therefore areas for possible intervention.

Another factor that might limit interpretation of the study was the sample. Regarding the sample characteristics, the participants were recruited from four different units which varied in location (South London and Tunbridge Wells) and were therefore likely to be diverse and representative. However, ethnicity was not captured so generalizability cannot be assumed. Also, there may have been important differences in demographic factors and access to services across units (i.e., difference between inner London and suburbs) which were not recorded and therefore not accounted for in the results. It is also important to be aware of the ways in which the selection criteria may have biased the current sample e.g. by not

approaching anyone where it was deemed as clinically inappropriate by the direct treatment team, and the fact that the inherent nature of the intervention required patients to be able to read and write. Furthermore, it is possible that those who dialysed on a 'twilight' shift (in the evening), although small in number, may have differed either on demographic or socio-economic dimensions, to those who dialysed at other times of the day. For example, it is possible this group were more likely to be in employment, younger and therefore fitter and healthier, and thus more inclined to agree to participate and adhere to requirements of the EW procedure. Since this subsection of patients was not approached, the results of the current study cannot be generalised to this group. Results of the trial phase were also limited by the small sample size, compared to other studies, and would require a larger sample to draw firm conclusions about the efficacy of the EW intervention.

It is also important to mention some limitations concerning the study's two different design phases. The first phase was cross-sectional with correlational analyses, which means the causative mechanism cannot be determined. The correlational analyses identified that negative illness perceptions and fatigue are significant predictors of distress, but cannot infer the direction of causality. It may be that, if a patient constructs a negative perception of their illness and/or is more fatigued, they are more likely to experience psychological distress as a result. However, negative illness perceptions and greater fatigue can also be interpreted as a manifestation of psychological distress. Since cross-sectional analysis relies on data from a snapshot in time, prospective, longitudinal studies would be required to examine whether distress fluctuates over time and would therefore substantiate which one of these is more likely. In addition, when considering correlational results, it is important to consider the possibility that a third unidentified, extraneous variable may be impacting on the relationship between the other two variables, which is often referred to as a 'tertium quid' (Field & Davey, 2005). There are an infinite of possible extraneous variables, independent of kidney failure and its treatment, some of which have been shown to influence psychosocial parameters, for example social support correlates with depression (Kimmel, 2000). It is impossible to account for all of these and many may change over time e.g., relationship status and financial circumstances. However, some more easily quantifiable disease-related variables could have been measured, and therefore controlled for in the results, including years since diagnosis, treatment with erythropoietin (a drug used to control anaemia) and compliance with dialysis.

In relation to the trial phase, the EW condition instructions required participants to focus the subject of their writing on their dialysis treatment, which assumed this to be their main stressor. However, other stressors may have been inflicting a higher amount of strain on a patients' life than their dialysis treatment or kidney problem and would make such a focussed intervention unlikely to have an effect. Future studies could therefore trial a similar procedure using different instructions, or give several options so patients can choose to write about a stressor of their choice. There is also an ongoing debate about the best form of control group to employ in disclosure studies. Norman et al (2004) argue in favour of asking the control group to write about positive experiences, since this is emotionally relevant and has face validity to reduce stress. They also point out the possible adverse effects of participants learning about and consenting to a disclosure study, and then being randomised to a control group that is not asked to disclose. However, this method does not enable comment on inhibition mechanisms, since positive writing can produce positive effects. To enable comment on inhibition mechanisms, the control group were asked to write about emotionally neutral, but still disease-related, topics. However, this also meant the control group was active and could have been considered an intervention in itself. A more complex design would have included the addition of a waiting list or treatment-as-usual group, in order to further help determine the precise effects of the EW intervention. Furthermore, patients were not isolated when writing and may have been aware of other participants completing the same procedure, which could have contaminated results. One way to prevent this would be to carry out a randomised cluster trial with several sites. However, this was not possible due to the limited number of sites granted access under the ethical agreement. Furthermore, such contamination was unlikely to have occurred in this instance since only a small sample number entered into the trial phase.

Finally, in terms of the trial phase, there were some barriers to implementing the writing intervention. First of all, unlike other studies which have used a private space, the participants were asked to complete the writing task whilst dialysing in the renal clinic, which is a public place and largely uncontrolled. This increased external validity but meant the procedure was subject to a number of real-world confounds, such as preoccupation with treatment, presence of others and frequent interruptions by members of staff or other patients. The presence of such confounding factors could be considered threats to internal validity and may have reduced effect sizes by increasing error variance. However, strict adherence to the EW procedure meant that initial recruitment into the trial phase was quite slow.

Some adaptations to the method were therefore permitted (for example, allowing patients to take the scripts home), in order to reach sample size. In addition, patients may have felt uncomfortable about disclosing extremely upsetting experiences whilst situated in a public place, or after being informed the scripts would be read by a member of the research team which possibly impacted on numbers consenting to take part in the trial phase.

4.5 Future Research

The section above outlines a number of possible directions for future research, many of which would overcome some of the limitations. This study also gained some important insights which warrant further analysis.

Firstly, the findings support the idea of a link between fatigue and distress. So far, researchers are confident in knowing that fatigue is a significant problem for dialysis patients (Horigan, 2012), but research examining the relationship between fatigue and psychosocial variables is not extensive. Further investigation is therefore required to determine whether distress and fatigue are consistently related in dialysis patients and the exact nature of this relationship, for example whether it operates at the biological (i.e., via inflammation markers), behavioural (i.e., via non-adherence to treatment and being unable to manage symptoms properly) or cognitive (i.e., via limitation in performing activities leading to a sense of diminished integrity and low independence and therefore helplessness) level. There is also the possibility that the relationship is reciprocal.

Future research could also investigate the feasibility of interventions designed to target illness perceptions, particularly beliefs about consequences, and determine whether this improves adaptive functioning. For example, Tsay, Lee & Lee (2004) found that an adaptation training programme helped improve perceived stress, depression and quality of life for ESRD patients. Illness perceptions are thought to be complex and dynamic, and are therefore constantly updated over time. Additional studies could investigate how the pattern of illness perceptions change, and at what point in the course of illness it is best to intervene. It might also be interesting to extend research to see if the same relationship between illness perceptions and distress exists in PD patients. Finally, illness perceptions could also vary according to personality and cultural factors (Kutner and Devins, 1998) which warrants more inquiry in this population.

Even though the statistical gains were slight, the current results suggest dialysis patients showed a positive response to the EW intervention. It would be important to replicate this study with a sample to enable survival analysis of the EW and neutral writing groups using a large multi-site trial. More recently, research into EW has placed a stronger emphasis on examining the ways people write and the types of individuals suited to EW. A larger sample would allow analysis of such moderators. The current data represent improvements over only 3 months of follow-up and maintenance of these effects over time is critical to improving long-term outcomes for patients with ESRD. Therefore, it would be important to conduct a longitudinal study to establish durability of effects over time. It would also be important to consider some of the already suggested modifications to the writing protocol, for example increasing flexibility, or focussing on those patients in early stages of dialysis, as well as perhaps increasing available staff and resources, in order to improve adherence and obtain larger effects.

It would be worthwhile conducting a qualitative analysis of the types of words used to explore differences in linguistic content. The Linguistic Inquiry and Word Count Software developed by Pennebaker & Francis (1996) is a program which analyses writing scripts in text format. It computes the percentage of words that reflect negative emotions, positive emotion, causation, insight and other dimensions. This can therefore show differences in word usage across a variety of categories including affective processing, cognitive processing, social processing, time and metaphysical. By analysing past scripts, Pennebaker, Mayne & Francis (1997) have found that when people used more positive-emotion words, and a moderate amount of negative words, the more their health improved. They also found the related to increases in words reflecting causality and insight. Pennebaker et al (1997) believe these linguistic changes reflect cognitive processes associated with encoding and storing features of the experiences ”in a more organised coherent and simplified manner…that reduced the associated emotional arousal” (p.864). Analysis of this type would therefore provide a useful insight into the mechanism of change and the degree of cognitive processing. Using a no treatment control group would help to further tease apart the effects of different conditions

Future studies could also consider modifying the paradigm used, for example by giving guidance on structure of writing or allowing more flexibility, in order to establish the optimal conditions for writing. It could adopt a similar method to qualitative studies which have asked participants to focus on concerns specific to dialysis patients e.g., freedom and control, social relationships, anxiety, role

function, energy and body image (Tong et al, 2009). We should also consider the possible future directions of EW in relation to technology, for example using a secure internet website to type instead of hand writing. This method has been tried and tested in previous studies with promising outcomes (e.g., Halpert, Rybin & Doros, 2010; Morgan et al, 2008). Alternative modalities could include using audio recorded statement or telephone interviews. A few studies have compared writing with talking into a tape recorder with comparable effects (Pennebaker & Seagal, 1999). Adequate discussion of appropriate times/setting for writing and more flexible approach could also be implemented to maximise the likelihood of adherence. However, it is important to establish treatment efficacy first (maximising internal validity) before establishing effectiveness (maximising external validity). Other studies which have applied the EW paradigm to a community-based setting have shown good results with regards to feasibility (Broderick et al, 2004).

Finally, in order to further establish treatment fidelity, it would be useful to ask participants some writing process questions e.g., how upsetting or uplifting they found it or how they think the writing has changed their thoughts or feelings. It is important to note that, in this study, qualitative responses were not collected in a systematic way and some participants did not wish to give a reason for withdrawal. Future studies could therefore establish feasibility in a more standardised way, for example by asking participants to what extent they found the task difficult, stressful, enjoyable and helpful, similar to Morgan, Graves, Poggi & Cheson's study (2008).

4.6 Conclusions

In spite of the limitations outlined in the section above, this study has a number of strengths. It was the first study to analyse correlates of distress using the GHQ-12 for dialysis patients, and to trial EW as a novel intervention in this patient group. The focus on distress, rather than depression, as the primary outcome measure, meant that there was no overlap in somatic symptoms. Also, the inclusion of illness perceptions enabled valid insights to be gained about their relation to distress and enhanced understanding of their relevance to EW effects. It was particularly important that emotional illness perceptions were discounted from the final analyses, which meant the illness perceptions variable represented a distinct scale of illness cognitions, with no influence of emotions.

Overall, the findings supported the well-established fact that HD patients suffer from high levels of physical and psychological distress, and further expanded on studies investigating psychosocial factors. The results concluded that fatigue and illness

perceptions are stronger predictors of distress than age or co-morbidity, and that, more specifically, beliefs about illness consequences predict distress levels. This advances existing work on quantifying distress in ESRD, informs clinicians of what to look out for and of who is likely to suffer distress, and signifies areas for potential intervention which could improve distress, and therefore illness outcomes.

Psychological treatments are becoming increasingly accepted, and effective for at least a subset of dialysis patients. Findings from this study add to this by showing that EW is feasible for use with dialysis patients, but with adaptations, and that it is potentially clinically effective with regards to reducing distress, improving illness perceptions, symptoms of pain and fatigue, and blood pressure. The broad psychological and physical health benefits (e.g., Smyth, 1998) together with these findings suggest that EW can produce health benefits in clinically distressed dialysis patients. Considering these data as pilot information, a larger multisite randomized controlled trial is certainly warranted. These current findings therefore provide a solid platform for future studies which should continue to explore this reactive support modality as a way of providing patients with an important tool for coping with distress related to dialysis treatment.

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Appendix A Letter of ethical approval

NHS
Health Research Authority
NRES Committee London - Camden & Islington
North East REC Office
Room 002
TEDCO Business Centre
Rolling Mill Road
Jarrow
Tyne & Wear
NE32 3DT

Telephone: (0191) 4283561

19 December 2012

Miss Jennifer Hunt
Trainee Clinical Psychologist
Camden & Islington NHS Trust
Institute of Psychiatry, KCL
Addiction Sciences Building, 3rd Floor
4 Windsor Walk, Denmark Hill, London
SE5 8AF

Dear Miss Hunt

Study title:	**A randomised controlled trial to assess the feasibility and efficacy of using an expressive writing intervention with patients on haemodialysis**
REC reference:	**12/LO/1858**
Protocol number:	**N/A**
IRAS project ID:	**113859**

Thank you for your letter of 14 December 2012, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Joan Brown, email address nrescommittee.london-camdenandislington@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as one Research Ethics Committee

A Research Ethics Committee established by the Health Research Authority

has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering Letter	Jennifer Hunt	11 December 2012
Evidence of insurance or indemnity	Gallagher Heath Letter	01 August 2012
Investigator CV	Miss Jennifer Hunt	02 November 2012
Other: GP Letter	1.0	10 October 2012
Other: CV - Professor Rona Moss-Morris		
Other: CV Joseph John Chilcot		
Other: CV Rachel Hilton		17 October 2012
Other: CV Thomas Ellice		23 October 2009
Other: CV Manus Cross		22 October 2012
Other: Insurance Policy	Zurich Municipal	20 July 2012
Other: Reviewer's Report	Idit Albert	14 September 2012
Other: Renal Project Board Steering Committee's Decision	Jonathon Olsburgh Email	17 July 2012
Participant Consent Form	2.0	06 December 2012
Participant Information Sheet	2.0	06 December 2012
Protocol	6.0	02 November 2012
REC application		02 November 2012
Response to Request for Further Information		14 December 2012

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

A Research Ethics Committee established by the Health Research Authority

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

12/LO/1858	**Please quote this number on all correspondence**

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely

p.p.
Ms Stephanie Ellis
Chair

Email:nrescommittee.london-camdenandislington@nhs.net

Enclosures: "After ethical review – guidance for researchers" *[SL-AR2]*

Copy to: *Ms Jennifer Liebscher, Institute of Psychiatry/South London and Maudsley NHS Foundation Trust King's College London*
Ms Karen Ignation, Guy's and St Thomas' NHS Foundation Trust

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Appendix B Guys & St Thomas' research and development approval

Guy's and St Thomas' NHS
NHS Foundation Trust

Research & Development
16th Floor Tower Wing
Guy's Hospital
Great Maze Pond
London SE1 9RT
Tel: 020 7188 7188

Dr Rachel Hilton
Guy's and St Thomas' NHS Foundation Trust
Guy's Hospital
Great Maze Pond
London
SE1 9RT
United Kingdom

15/01/2013

Dear Dr Hilton

Title: A randomised controlled trial to assess the feasibility and efficacy of using an expressive writing intervention with patients on Haemodialysis

In accordance with the Department of Health's Research Governance Framework for Health and Social Care, all research projects taking place within the Trust must receive a favourable opinion from an ethics committee and approval from the Department of Research and Development (R&D) prior to commencement.

- **Ethics Number: 12/LO/1858**
- **Sponsor: Kings College London**
- **Funder: None**
- **End Date: 30/06/2014**
- **Protocol: Version 6.0 - 02/11/2012**
- **Site: Guy's and St Thomas' NHS Foundation Trust**
- **R&D Approval Date: 14/01/2013**
- **Chief Investigator: Ms Jennifer Hunt**

NHS permission for the above research has been granted on the basis described in the application form, protocol and supporting documentation as listed in the ethics letter of favourable opinion letter dated 19/12/2012. I am pleased to inform you that we are approving the work to proceed within Guy's and St Thomas' NHS Foundation Trust and that the study has been allocated the Trust R&D registration number **RJ113/N009**. Please quote the R&D registration number in any communications with the R&D Department regarding your project.

Whilst the Trust takes on non funded research without charge for sponsorship, research management and governance or research costs we encourage all research to be funded and particularly encourage UKCRN portfolio eligible research. Prior to your next research proposal please contact the R&D department about portfolio eligibility and how to gain funding for research so as to ensure that the study can gain appropriate funding prior to your research application.

Conditions of Approval:

- The principal investigator must ensure that the recruitment figures are reported.
- The principal investigator must notify R&D of the actual end date of the project.
- R&D must be notified of any changes to the protocol prior to implementation.
- The project must follow the agreed protocol and be conducted in accordance with all Trust Policies and Procedures especially those relating to research and data management.
- Members of the research team must have appropriate substantive or honorary contracts with the Trust prior to the study commencing. Any additional researchers who join the study at a later stage must also hold a suitable contract.

Data Protection:
Please ensure that you are aware of your responsibilities in relation to The Data Protection Act 1998, NHS Confidentiality Code of Practice, NHS Caldicott Report and Caldicott Guardians, the Human Tissue Act 2004, Good Clinical Practice, the NHS Research Governance Framework for Health and Social Care, Second Edition April 2005 and any further legislation released during the time of this study.

The Principal Investigator is responsible for ensuring that Data Protection procedures are observed throughout the course of the project.

If the project is a clinical trial under the European Union Clinical Trials Directive the following must also be complied with:

1. The EU Directive on Clinical Trials (Directive 2001/20/EC) and UK's implementation of the Directive: The Medicines for Human Use (Clinical Trials) Regulations 2004;
2. The EU Directive on Principles and Guidelines for Good Clinical Practice (EU Commission Directive 2005/28/EC); and UK's implementation of the Directive: The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006;
3. If a clinical trials team has to keep a subject in a department" out of hours" for whatever reason, the Senior Nurse for the Hospital should be informed of their presence – as should the Resuscitation Team.
4. For CtiMP studies hosted by GSTFT, the sponsor is responsible for reporting updates and providing updated documents related SMPC at this site

Amendments:
Please ensure that you submit a copy of any amendments made to this study to the R&D Department.

ISRCTN registration:
If appropriate it is recommended that you register with the Current Controlled Trials website http://isrctn.org/. Find out more about registering for an International Standard Randomised Controlled Trial Number (ISRCTN) as part of the Portfolio application process. Non-commercial studies with an interventional component that are eligible for NIHR CRN support can register for an ISRCTN for free via the Portfolio Database.

Annual Progress Report:
It is obligatory that an annual report is submitted by the Chief Investigator to the research ethics committee, and we ask that a copy is sent to the R&D Department. The yearly period commences from the date of receiving a favourable opinion from the ethics committee.

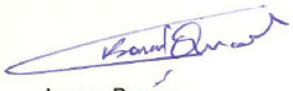
Please submit a copy of the progress report on the anniversary of the Ethics favourable opinion **(19 Dec).**

Should you require any further information please do not hesitate to contact us.

In line with the Research Governance Framework, your project may be randomly selected for monitoring for compliance against the standards set out in the Framework. For information, the Trust's process for the monitoring of projects and the associated guidance is available from the Trust's intranet or on request from the R&D Department. You will be notified by the R&D Department if and when your project has been selected as part of the monitoring process. No action is needed until that time.

Thank you for registering your research project.

Yours sincerely



Jessey Bonsu
R&D Governance Coordinator

cc: Kings College London
cc: Ms Jennifer Hunt

Appendix C Patient information sheet

Guy's and St Thomas' NHS
NHS Foundation Trust

Patient Information Sheet
Version 2.0, dated 06/12/12

Study title: The Effects of Expressive Writing on Haemodialysis Patients

Principal Investigator: Miss Jennifer Hunt
Co-investigators:
Dr Joe Chilcot
Dr Rachel Hilton
Prof Rona Moss-Morris

Invitation

You are being invited to take part in the above research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

1. What is the purpose of the study?

We are conducting a study to examine the effects of a technique known as "expressive writing", when used with patients who are undergoing dialysis treatment. This technique has been used with lots of other groups of patients before, such as those with arthritis, and it has been shown to have positive effects on their physical health and psychological well-being. The information from this study will help us to know whether this technique can be applied to patients with kidney failure and whether it has the same benefits for them.

2. Why have I been invited?

You have been invited because you are a patient being treated for kidney failure with hemodialysis and are under the care of the Guy's renal team. We are inviting all patients in the renal units under the care of Guy's & St Thomas' NHS Trust to take part. We hope approximately 200 people will take part in the study.

3. Do I have to take part?

No! It is up to you whether you take part. If you agree to take part you will be given this information sheet to keep and be asked to sign a consent form. **If you decide to take part you are still free to withdraw at any time and without giving a reason**. This will not affect the standard of care you receive.

4. What will happen to me if I take part?

If you agree to take part;

- One of the members of the research team (either a medical student or Clinical Psychology Trainee) will ask you to fill out a number of questionnaires. This will help us to understand the different factors, which may contribute to your psychological well-being including your mood, level of pain, fatigue, distress and beliefs about your illness. These will take approximately 15-20 minutes to complete.

- We would also like to collect some basic data from medical notes (your most recent blood results)

- Once these questionnaires are completed, you may be randomly assigned to one of two different writing groups, and be asked to carry out a writing procedure. This will involve writing about aspects of your kidney problem and dialysis treatment for 15 to 20 minutes, whilst dialysing, on three consecutive dialysis days (e.g., Monday, Wednesday and Friday or Tuesday, Thursday and Saturday). Writing whilst on dialysis may sound challenging, but we have tested this out with some patients and they were pleased to find they could do it.

- If you are in one of the writing groups, when the third and final writing session has ended, you will be asked to complete the same set of questionnaires and we will ask you a few questions about how you found the writing procedure.

- Following this, you will be asked to complete the same set of questionnaires another two times (once after 3 months, and finally again after 6 months).

At any stage of the project if you feel you might be experiencing any kind of distress as a result of writing about your health condition and treatment, we can discuss the possibility of getting some help or support for you. This professional help might come from one of the Clinical Psychologists attached to the renal units working for Guys & St Thomas' NHS Trust.

You will not be required to attend any extra clinics or have additional tests or receive extra drugs or medicines. Your standard dialysis or transplant related treatment will NOT be affected in any way by participating or not participating in the study

5. **What do I have to do?**

What we would like you to do is to agree for us to collect data about your health and to fill out the questionnaires given to you. We would also like you to agree to take part in the writing sessions, if you are asked to. In this case, instructions and writing instruments will be provided when you come in for your usual clinic visits. If you are in one of the writing groups we would like to look at what you

write to evaluate the kind of words people use. It will not be possible to identify you from what you write as no names will be used on the writing material.

There are no lifestyle restrictions or any dietary restrictions exclusively as a result of participating in the study.

6. Is there a **drug or procedure being tested?**

There are no drugs, medical devices or other treatments being tested in this study and there will be no change to your treatment or standard of care.

7. Are there any **side effects from taking part?**

There are no side effects of taking part in this study, because we are not testing any new medicines.

8. **What are the possible disadvantages and risks of taking part?**

There are no risks to your health or any changes to your treatment if you agree to take part in this study. Your will be required to complete some questionnaires and may be required to take part in the writing sessions which would require some of your time. However, everything we require you to do will take place during your routine clinic visits. In addition, we will not ask you to fill out questionnaires or write at the beginning or end of your dialysis treatment sessions. You will be able to take a short break during the writing sessions, if needed.

Although unlikely, there is a small risk of distress caused by the writing sessions as you may become aware of an issue that you had not previously thought of. For this reason, the writing scripts will be screened by the research team after each writing session has been completed. In the case of any risk issues being identified (concerns about harm to yourself or others), it would be necessary to pass this information on to the appropriate services (e.g., doctor or other health professional), in accordance with NHS policy. In this case, we may have to break confidentiality in order to help keep you safe but we would inform you of doing so. If for any reason you feel uncomfortable whilst taking part, you are reminded of your right to withdraw at any time. In addition, if you wish to talk to your consultant or a psychologist at any stage of the study, arrangements can be made.

9. **What are the possible benefits of taking part?**

By agreeing to take part and filling out the questionnaires, you will be contributing towards a better understanding of the effects dialysis treatment has on psychological well-being. This will in turn help researchers and health professionals to improve the care of patients undergoing dialysis treatment in the future.

If you are asked to take part in the writing sessions, it is possible this will

improve your physical health and some aspects of your psychological well-being. However, this cannot be guaranteed. If it is found to be beneficial, this study may help researchers to develop this procedure so that it can be used with future patients undergoing dialysis treatment, therefore improving their overall quality of life.

10. **What if new information becomes available?**

Sometimes during the course of a research project, new information becomes available about the dialysis, transplantation and quality of life with either treatment. If this happens, your research doctor/nurse will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your care will continue as before. If you decide to continue in the study you will be asked to sign an updated consent form.

11. **What happens when the research study stops?**

At the end of the research you care remains the same. We would like to have the opportunity to contact you with information regarding the findings of the project.

12. **What if something goes wrong?**

Since the study is only recording information about you, and asking you to fill in questionnaires or be interviewed, it is very unlikely that something will go wrong. However if you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will be available to you.

13. **Will my taking part in this study be kept confidential?**

All the information recorded will be strictly confidential and kept in accordance with the Data Protection Act 1998, and used only by clinicians and researchers working within the research team. Data from the study regarding you will be stored anonymously. We will contact your GP to inform them of your participation in the research.

14. **What will happen to the results of the research study?**

When the study is completed we intend to publish the results in order to help other researchers and health care professionals understand the well-being of dialysis patients. We would also aim to show these results to other kidney doctors and dialysis units, so that other dialysis units would be aware of the results. You will not be named in any reports or results we publish.

15. **Who is organising and funding the research?**

This study is being conducted by academic staff and students at the Institute of Psychiatry (IoP), part of King's College London. It has been organised by a Trainee in Clinical Psychology, Jennifer Hunt, supervised by Dr Joe Chilcot and Professor Rona Moss-Morris (King's College London). The research team is not being paid for including and looking after the patients taking part in the study. The IoP are sponsoring this study.

16. **Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed by the NRES Committee London – Camden and Islington.

17. **Contacts for Further Information**

If you do require additional information, please use the contacts below:

For independent advice you can contact PALS (Patient Advice and Liaison Service) by visiting : www.pals.nhs.uk or by contacting the PALS office at Guy's and St Thomas' Hospitals:

Patient Advice & Liaison Service, Patient Information Team, KIC, Ground floor, North wing, St Thomas' Hospital, Westminster Bridge Road, London, SE1 7EH

For information about the study:

Dr Joe Chilcot (project supervisor)
Email - Joseph.chilcot@kcl.ac.uk
Tel - 020 7188 2597

Jennifer Hunt (trainee clinical psychologist)
Email – Jennifer.hunt@kcl.ac.uk
Tel - 020 7848 0223

Thank you for reading this.

You will be given a copy of the information sheet and a signed consent form to keep.

Appendix D Consent form

Guy's and St Thomas' NHS
NHS Foundation Trust

CONSENT FORM

Study title: The Effects of Expressive Writing on Haemodialysis Patients

Principal Investigator: Miss Jennifer Hunt
Co-investigators: Dr Joe Chilcot, Dr Rachel Hilton & Prof Rona Moss-Morris

	Please initial box
1. I confirm that I have read and understand the information sheet dated **06/12/12 (version 2)** for the above study and have had the opportunity to ask questions.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	☐
3. I understand that sections of my medical notes and data collected during the study may be looked at by responsible individuals from the research team, who will collect information concerning my health, and by regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data.	☐
5. I understand that I will be asked to complete a set of questionnaires (five in total) once and may be asked to complete them again another three times and I agree to do this.	☐
6. I understand I will be asked once to provide some demographic information about myself (age, ethnicity, working status and marital status).	☐
7. I understand that I might be asked to carry out a writing procedure which involves writing about aspects of my renal problem and dialysis treatment for 15 to 20 minutes, whilst dialysing, on three consecutive clinic days and I agree to complete them *if required*.	☐
8. I understand that I will be asked some feedback questions after the writing procedure has finished.	☐
9. I agree to be contacted in the future to follow-up this study if required.	☐

..... Name of Patient	..... Date	..... Signature
..... Name of Person taking consent	..... Date	..... Signature (if different from researcher)
..... Researcher	..... Date	..... Signature

1 copy for patient; 1 copy for researcher; 1 copy to be kept with hospital notes

Consent form, version 2.0, 06/12/12, REC Number: **12/LO/1858** 1

Appendix E GP letter

Guy's and St Thomas' NHS
NHS Foundation Trust

Guy's Hospital
St Thomas Street
London SE1 9RT
Tel: 020 7188 7188

Date

Address

Please reply to :

Jennifer Hunt
Trainee Clinical Psychologist
Institute of Psychiatry
Addiction Sciences Building
4 Windsor Walk
London
SE5 8AF

Tel +44 (0) 20 7848 0223
Fax +44 (0) 20 7848 0860
Email: jennifer.hunt@kcl.ac.uk

Dear Dr XX,

DATE

Patient Name, DOB

The above patient of yours is currently participating in our research project *The Effects of Expressive Writing on Haemodialysis Patients (REC Number*: **12/LO/1858**), following an initial meeting with them at the [UNIT] on [DATE]. I enclose a copy of the Patient Information Sheet for further information. This project has been approved by the NRES Committee London – Camden and Islington.

Please do not hesitate to contact me if you have any queries.

Yours sincerely,

Jennifer Hunt
Trainee Clinical Psychologist

GP Letter, version 1.0, 10/10/12, REC Number: **12/LO/1858**

Appendix F Clinical pro forma

Clinical Pro Forma

Anonymity Number_____

Age: _____

Dialysis Start Date:

Previous Transplant; YES
NO

Co-morbidity Score (baseline only)_____

Diagnosed or treated for depression Y/N

If yes, treatment _____

		Baseline	3 months	6 months
	Date:→			
	(unit)			
Hb				
Albumin				
CRP				
Kt/V				
Serum Phosphate				
BP				
Potassium				
PTH				
Ferritin				

Appendix G Demographic questionnaire

Patient Questionnaire

Anonymity Number: _____

Date (DD/MM/YY): _____

Please answer the following questions by circling the number associated with your response, unless otherwise stated. If for any reason you do not wish to answer a question please leave it blank.

1. Gender
   - Male 1
   - Female 2

2. Date of Birth (DD/MM/YYYY) _____

3. Are you currently taking EPO (erythropoietin) at this present time?
   - Yes 1
   - No 2
   - I do not know 3

4. Are you currently on the transplant list?
   - Yes 1
   - No 2
   - I do not know 3

5. Do you exercise regularly?
   - Yes more than 3 times per week 1
   - Yes less than 3 times per week 2
   - No I do not 3

6. Do you smoke?
   - Yes 1
   - Ex-smoker 2
   - No 3

7. Are you currently?
   - Married 1
   - Widowed 2
   - Divorced 3
   - Separated 4
   - Living with partner 5
   - Single parent 6
   - Never Married 7
   - Single 8
   - Other (_____) 9

Version 1.0

8. During the past month were you?

Working Full time	1
Working Part time	2
Retired	3
Full time house keeping	4
Unemployed	5
Self employed	6
Not working due to ill health	7
None of the above	8

9. Are you able to work now?

Yes	1
No	2
Retired	3

10. What members of family live with you?

Live Alone	1
Live with spouse/partner	2
Live with spouse/partner and children	3
Single parent with children	4
Live with other relatives	5
Live with friends	6

Version 1.0

Appendix H Questionnaire booklet

Anonymity Number

GENERAL HEALTH QUESTIONNAIRE

We would like to know how your health has been in general over the past few weeks.

Please answer ALL the questions simply by underlining the answer you think best applies to you. Remember that we want to know about present and recent health.

HAVE YOU RECENTLY;

1.	been able to concentrate on whatever you're doing	Better than usual	Same as usual	Less than usual	Much less than usual
2.	lost much sleep due to worry	Not at all	No more than usual	More than usual	Much more than usual
3.	felt that you are playing a useful part in things	More so than usual	Same as usual	Less useful than usual	Much less useful
4.	felt capable of making decisions about things	More so than usual	Same as usual	Less useful than usual	Much less capable
5.	felt constantly under strain	Not at all	No more than usual	Rather more than usual	Much more than usual
6.	felt you could not overcome your difficulties	Not at all	No more than usual	Rather more than usual	Much more than usual
7.	been able to enjoy your normal day-to-day activities	More so than usual	Same as usual	Less so than usual	Much less than usual
8.	been able to face up to your problems	More so than usual	Same as usual	Less so than usual	Much less than usual
9.	been feeling unhappy and depressed	Not at all	No more than usual	Rather more than usual	Much more than usual
10.	been losing confidence in yourself	Not at all	No more than usual	Rather more than usual	Much more than usual
11.	been thinking of yourself as a worthless person	Not at all	No more than usual	Rather more than usual	Much more than usual
12.	been feeling reasonably happy, all things considered	More so than usual	About the same as usual	Less so than usual	Much less than usual

Anonymity Number

Belief Illness Perception Questionnaire

For the following questions, please mark a number that best corresponds to your views:

a. How much does your kidney problem affect you currently?

No affect at all 0 1 2 3 4 5 6 7 8 9 10 Severely affects me currently

b. How long do you think your kidney problem will continue?

A very short time 0 1 2 3 4 5 6 7 8 9 10 Forever

c. How much control do you feel you have over your kidney problem?

Absolutely no control 0 1 2 3 4 5 6 7 8 9 10 Extreme amount of control

d. How much do you think your treatment can help your kidney problem?

Not at all 0 1 2 3 4 5 6 7 8 9 10 Extremely helpful

e. How concerned are you about your kidney problem?

Not at all concerned 0 1 2 3 4 5 6 7 8 9 10 Extremely concerned

f. How well do you feel you understand your kidney problem?

Don't understand at all 0 1 2 3 4 5 6 7 8 9 10 Understand very clearly

g. How much does your kidney problem affect you emotionally? (e.g. does it make you angry, scared, upset or depressed?)

Not at all affected emotionally	0	1	2	3	4	5	6	7	8	9	10	Extremely affected emotionally

Please list in rank-order the three most important factors that you believe caused your kidney problem. The most important causes for me:-

1. _____

2. _____

3. _____

Anonymity Number

PHQ-2

Over the last 2 weeks, how often have you been bothered by any of the following problems?

(Use "✔" to indicate your answer")	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3

Anonymity Number

VAS- Pain

a. Please rate your pain by marking one number that best describes the

intensity of your pain at rest.

No Pain 0 1 2 3 4 5 6 7 8 9 10 Extreme Pain

b. Please rate your pain by marking one number that best describes the

intensity of your pain on movement.

No Pain 0 1 2 3 4 5 6 7 8 9 10 Extreme Pain

c. Please rate your pain by marking one number that best describes the

unpleasantness of your pain.

Not at all 0 1 2 3 4 5 6 7 8 9 10 Very Unpleasant
unpleasant

Anonymity Number

FATIGUE SCALE

	Less than usual	No more than usual	More than usual	Much more than usual
Do you have problems with tiredness?	0	0	1	1
Do you need to rest more?	0	0	1	1
Do you feel sleepy or drowsy?	0	0	1	1
Do you have problems starting things?	0	0	1	1
Do you lack energy?	0	0	1	1
Do you have less strength in your muscles?	0	0	1	1
Do you feel weak?	0	0	1	1
Do you have difficulty concentrating?	0	0	1	1
Do you make slips of the tongue when speaking?	0	0	1	1
Do you find it more difficult to find the correct word?	0	0	1	1
	Better than usual	No worse than usual	Worse than usual	Much worse than usual
How is your memory?	0	0	1	1

PART B: Service Evaluation Project

Coming back for more: What can we learn from clients who re-present for step-3 treatment in the Lambeth IAPT service?

Jennifer Hunt

Supervised by: Dr Nick McNulty

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Abstract

Since the Increasing Access to Psychological Therapies (IAPT) scheme was established, a few studies have looked at drop-out rates but there is little research investigating those who are re-referred for a second course of therapy. The aim of this audit was to explore the reasons clients re-present for therapy within Lambeth IAPT, to find out whether the second treatment episodes were useful, and whether any factors were associated with usefulness. Data was collated and analysed from the existing IAPTus database on 82 clients, who met eligibility criteria, which was supplemented by data collected from questionnaires e-mailed out to therapists within the service. The results indicated that clients who had completed a second course of treatment since 2009, were most likely to be White females, aged 25-34 with a diagnosis of depression on both occasions, many with a secondary diagnosis of personality disorder or associated traits. They were most likely to require more treatment because their original symptoms had continued or worsened. Approximately 45% of clients recovered during their second treatment, regardless of initial treatment outcome. Within the group who did not recover first time, differences between those who did and did not recover second time were examined. This showed that the Generalised Anxiety Disorder Questionnaire (GAD-7) scores at the end of the first treatment episode were significantly higher for the group who did not recover. However, this difference was not large enough to allow generation of a 'cut-off' point on the GAD-7 to distinguish between the groups. These findings are discussed in terms of clinical and service implications. Recommendations are made, particularly in the context of the recently proposed IAPT expansion to encompass more complex referrals. It is hoped this research framework can be replicated and applied to similar audits in future.

1.0 INTRODUCTION

1.1 Mental Health Problems in Primary Care

The high prevalence of mental health problems in the UK has generated increasing concern, particularly over the past ten years. According to the Adult Psychiatric Morbidity Survey (McManus et al, 2007), 16% of working age adults in the UK have a mental illness. A report by the World Health Organisation (2001) recognised the huge burden presented by mental health problems and recommended treatment should be widely based in primary care services. Goldberg and Gournay (1997) designed a useful typology of mental health disorders which made a distinction between 'severe' and 'common mental health disorders' (e.g., schizophrenia and personality disorder versus depression and anxiety disorders). Bower and Gilbody (2005) consider this conceptualisation in their paper, which proposes that the 'common disorders' be viewed as the main focus and remit of primary care services.

A study by the Sainsbury Centre for Mental Health, (2003) found that approximately 76% of individuals with common mental health problems were not receiving any form of treatment in the year 2000. This was one of the statistics which prompted Lord Layard's highly influential report in 2005, proposing a change to the way mental health problems are managed within the National Health Service (NHS) This report highlighted the fact that mental illness in the UK not only causes misery and distress for a large percentage of the population, but also creates a huge drain on the economy as a consequence of reduced output.

1.2 NICE Guidelines

Since the invention of modern psychiatric drugs in the 1950s, effective psychological treatments such as cognitive-behavioural therapy (CBT) have been developed and refined for use with a variety of mental health problems. CBT is a structured, goal-based talking therapy largely rooted in the cognitive theory of depression, originally developed by Beck in 1970. CBT involves the therapist working collaboratively with the client through a process of 'guided discovery' with the ultimate goal being for the client to understand how their problems are maintained through a vicious cycle of negative thoughts, feelings and behaviours and to teach them skills which enable them to break out of this cycle.

In 2004, the National Institute for Health and Clinical Excellence (NICE) systematically reviewed the evidence for the effectiveness of a variety of

interventions for common mental health disorders, the results of which suggested that psychological therapy (such as CBT) and combined therapies (such as CBT and medication together) are effective for treating both anxiety and depression. In addition, several meta-analyses have shown that depressed clients treated with both drugs and CBT have significantly better outcomes than waiting list controls (e.g., DeRubeis, Gelfand, Tang & Simons, 1999). Furthermore, research indicates that patients favour talking therapies when given the choice (Warner, Mariathasan, Lawton-Smith, & Samele, 2006).

Following these convincing findings, NICE published a series of clinical guidelines (e.g., NICE, 2004a, 2004b) which advocate both the prescription of medication and the application of CBT as optional treatments for depression and all anxiety disorders. In light of evidence that some individuals respond well to 'low intensity' interventions, the guidelines suggest a 'stepped-care' approach to the delivery of these treatments (see Figure 1 below). This means matching the level of care intensity to the severity of the disorder so that those with mild symptoms of depression and anxiety are offered an assessment, support, psycho-education and active monitoring (step 1); those with mild to moderate symptoms are offered 'low intensity' treatment (in the form of guided self-help and computerised CBT); and those with moderate to severe symptoms are offered a combination of antidepressant medication and 'high intensity' psychological interventions (either interpersonal therapy, or individual CBT) (step 3). Finally, those who have more complex needs that cannot be treated at step 3 are referred to specialist mental health services that can provide multi-disciplinary care.

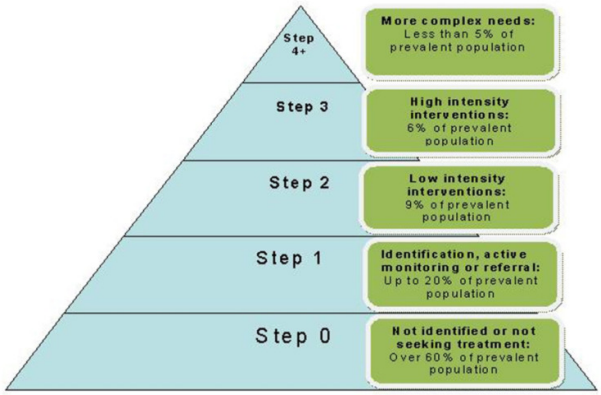

Figure 1. A diagram representing the 'stepped care model' used for treating common mental health problems in primary care in the UK (NICE, 2011)

1.3 Development of Increasing Access to Psychological Therapies (IAPT)

Following development of the NICE guidelines, economists and clinical researchers used a cost-benefit analysis to argue that investment in psychological therapies would largely pay for itself by reducing other depression and anxiety-related public costs and increasing revenues with fewer state benefits and more people working (e.g., Layard, Bell, Clark, Knapp & Mayraz, 2007). In response, the UK government pledged a commitment to increase the availability of evidence-based psychological treatments and in 2006, decided to fund two projects piloting a scheme to put this idea into practice (Clark et al, 2009; Richards & Suckling, 2009). Following their success, in 2007 it was announced that the government would fund a national roll-out of this initiative .The scheme would aim to train at least 3,600 new psychological therapists between 2008 and 2011 and deploy them, along with existing clinicians, in new psychological treatment services for patients with depression and anxiety disorders (Department of Health, 2008).

The general framework for IAPT services specifies several key principles including; the option of access through self-referral as well as referral by a general practitioner, a person-centred assessment that establishes key problems and goals for therapy, access to an employment adviser if employment is identified as an issue, and weekly supervision for therapists (Department of Health, 2008). There is also an emphasis on obtaining outcome data which means therapists are required to administer patient-reported outcome (PRO) measures at each contact with the client. This has enabled on-going monitoring and evaluation of performance, as well as measurement of financial benefits.

The introduction of the IAPT programme has marked an important shift in the focus on public mental health and well-being and has recently been described as “one of the most important advances for NHS services in a generation” (as cited in Ghosh, 2009, p. 186). Since it was first implemented, IAPT services have been established in 95% of primary care trusts (PCTs), trained 4,000 new therapists in CBT, seen 399,460 people (compared to a target of 400,000), moved 13,962 off sick pay and/or state benefits (compared to a target of 11,100) and have recovery rates approaching 45 % (compared to a target of 50%) (Clark, 2011). However, the scheme is still in its’ relative infancy and a recently established ‘second phase’ aims to develop certain aspects of the programme, for example, updating clinicians’ skills in non-CBT based therapies and broadening access to sub-sections of the

population such as older adults and ethnic minorities. Further initiatives are to provide specialist training for therapists to help manage patients with chronic health problems and medically unexplained symptoms (Department of Health 2011a, 2011b) and to extend services to provide help for those with more complex or severe mental health problems, such as bipolar disorder and personality disorder. Finally, a new version of the IAPT programme for children and young people is in the process of implementation.

1.4 Dealing with Relapse

This service evaluation is focussed on those clients who have re-presented for step-3 treatment at Lambeth IAPT since September 2009 and July 2012, and therefore includes a high proportion of those who have suffered a 'relapse'. It is now widely recognised that depression is a recurrent problem and that patients who suffer from an initial episode of depression have a high likelihood of experiencing another episode at least once within their lifetime (Keller, Lavori, Lewis & Klerman, 1983). Research has shown that following recovery from an initial episode, depressive symptoms often persist (known as 'residual' symptoms) and can trigger the onset of an additional episode (or 'relapse') despite the prolific use of on-going treatment using anti-depressant medication (e.g., Ramana et al, 1995). Since these findings emerged, support has accumulated for CBT as a viable alternative to medication for preventing depressive relapse. For example, the Cambridge-Newcastle study (Paykel et al, 1999) compared a control group receiving clinical management to a treatment group receiving clinical management plus 16 sessions of CBT over 20 months with two booster sessions. Relapse rates were lower for the CBT group after treatment (29% compared to 47%). A follow-up study (Paykel et al, 2005) showed that these effects gradually diminished over time, although the reduced relapse rates in the CBT group outlasted the control group.

Questions remain regarding the mechanism integral to CBT which actively lessens the likelihood of relapse. A complex analysis was undertaken following the Cambridge-Newcastle study (Teasdale et al, 2001) which examined possible cognitive mechanisms contributing to change and found that movement from extreme cognitions to more balanced cognitions was a key factor. Another possibility is that CBT provides a coping framework to empower the patient and provide them with active strategies to employ when their symptoms are starting to return or worsen (Paykel, 2007). Currently, the CBT protocols adopted by IAPT services outline relapse prevention as an important part of treatment and dedicate

the final three or four treatment sessions to exploring potential warning signs of a relapse. This includes reviewing coping strategies and collaboratively building a treatment 'blueprint' for patients to take away with them and refer to in the future.

Research studies examining patient variables which heighten the likelihood of relapse have mostly focussed on clinical features of the disorder (Judd, 1997). These variables include the number of past depressive episodes, the quality of remission at 3 or 6 months and psychiatric co morbidity (see below) (Segal, Pearson & Thase, 2003). Such findings have led to development of cognitive models of relapse vulnerability, the most prominent being Teasdale's Differential Activation Hypothesis (Teasdale, 1988). This theory suggests that individuals who have previously suffered from depression, are prone to the negative patterns of thinking (or 'depressogenic schema') being activated. In addition, the events that trigger this activation become less significant at each moment of relapse (also known as the 'kindling effect'). This had led to the development of modified CBT therapies such as mindfulness-based cognitive therapy or MBCT (Teasdale, Segal & Williams, 1995; Teasdale, 1995) which focuses on the relationship one has towards their thoughts, rather than their specific content, which has good evidence for preventing relapse (Teasdale et al, 2000).

Research shows the long-term clinical course of anxiety disorders is less clear, partly due to ongoing diagnostic changes for categories such as GAD (Schweizer, 1995) and as well as difficulties defining criteria for recovery or remission (e.g., Keller et al, 1994). However, according to recent surveys such as the National Comorbidity Survey Replication, anxiety disorders are the most common of all psychological disorders and research illustrates that these disorders tend to be chronic (Yonkers et al, 1998, Yonkers, Dyck, Warshaw & Keller, 2000; Yonkers, Dyck & Keller, 2001). It is therefore highly likely that a client with an anxiety disorder such as panic disorder or GAD, will relapse following initial remission. Furthermore, it is common for anxiety disorders to be co-morbid with depression (Kessler, Chiu, Demler & Walters, 2005), which is in turn associated with higher relapse rates (Schaffer et al, 2012).

1.5 Previous Research on Re-referral to IAPT

Previous research concerning patients who re-refer to IAPT for further treatment is limited, with the majority of research focussing on premature termination of therapy by patients. Drop-out rates are routinely reported as high (e.g., Wierzbicki & Pakarik, 1993) and are detrimental to the overall service efficacy, representing a

waste of resources and continued psychological distress. This research has failed to find any simple demographic characteristic which consistently predicts client drop-out rates (Garfield, 1994), apart from socio-economic variables (Grilo et al, 1998). A recent small study by Cairns (2013) examined the re-referral patterns and complexity level of patients who access the service for more than one episode of treatment, in order to establish what clinical factors distinguish this client population. The study generated descriptive statistics on a random sample of 50 clients who re-referred between June 2009 and June 2010 and found that clients did not differ in the route to which they accessed the service, and that a high proportion had no contact with the service at all, despite re-referral. The sample analysed were also more likely to present with co-morbidity, depression with anxiety and DSM-IV disorders, and increasing levels of complexity (for example history of abuse, mental disorder and drug and alcohol problems). Finally, the results showed that only a small number of those re-referred (16/50) went on to complete treatments, and that those who did, showed a marked preference for a counselling intervention.

1.6 Aims of Study

Since January 2011, the Lambeth IAPT service has treated approximately 2500 people at step-3 level and achieved an average recovery rate of 43%. However, the service has noted that a proportion of clients are re-presenting for more than one episode of treatment. The aim of this audit was to explore the reasons that clients re-present for a second episode of treatment within the IAPT service and to discover whether these second episodes are useful (in terms of service definition of recovery, and therapist ratings). The audit also aimed to discover any factors associated with the rate of re-presentation to see whether this information could be used to identify those less likely to benefit from a second treatment episode, and therefore help to enhance service efficiency.

2.0 METHODS

2.1 Setting

This audit was commissioned by the IAPT service based in Lambeth, a borough of South London. Initially, the intensive (step 3) element of the service was designed to offer one course of CBT therapy as a short-term intervention (usually between 10 and 20 weekly sessions) for adults experiencing depression and anxiety, in line with NICE guidelines. In August 2012, the service was successful in tendering to provide an integrated Primary Care Talking Therapy Service offering a wide range of psychological treatments including CBT for those with suspected or diagnosed severe or common mental health disorders, as well as counselling for those with psychological distress due to adjustment difficulties. In line with the aims outlined for IAPT's 'second phase' (2011), the service has consequently expanded its' client base and offers further therapy choices such as MBCT and interpersonal therapy as well as links to community and voluntary sectors. A specialist employment consultancy, ('Status') offers advice on employment and receives referrals for those who are out of work or experiencing issues retaining their existing job.

In terms of routes to treatment, the typical care pathway begins with a telephone triage appointment lasting 20 to 30 minutes during which the assessor, together with the client, can determine what would be the most suitable type of treatment for the identified problem. Computerized CBT, guided self-help and group workshops are offered as first line treatments for those with mild to moderate disorders who have not tried CBT before. Those with more severe difficulties or who have completed a course of 'low intensity' or 'step-2' treatment and failed to recover are then offered one-to-one sessions of CBT with a 'high intensity' or 'step 3' therapist.

2.2 Outcome Measures

The outcome measures used for this study were those which are mandated nationally for IAPT services to collect and monitor client outcomes, namely the Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer & Williams, 2001) and the GAD-7 Spitzer, Kroenke, Williams and Lowe, 2006). The PHQ-9 is designed to measure the severity of nine depressive symptoms on a Likert scale, in-line with the DMS-IV criteria for a psychiatric diagnosis. It is a well-validated scale (Kroenke et al, 2001) with good sensitivity to change (e.g., Lowe, Kroenke, Herzog & Grafe, 2004). The GAD-7 is a brief, valid and reliable tool to assess the severity of seven anxiety symptoms, also answered on a Likert scale.

2.3 Sample

A retrospective search was conducted on the 'IAPTus' database (an electronic database used by Lambeth IAPT to record data for clients entering the service and monitor their progress through the care pathway) which identified those clients who had completed more than one course of treatment at step 3 level, since September 2009 and July 2012. This date was used since it marked the time when data began to be consistently and accurately recorded. This generated a list of roughly 160 clients.

Each client on the list then had to be checked to ensure the sample was a true and accurate representation of those who had re-presented for a 'treatment episode'. Clients who were discounted included those whose 'second episode' referred to attendance at a group or employment advice; those who had seen therapists who were no longer employed by Lambeth IAPT for both episodes of treatment; and those whose first or second episode consisted of an assessment only. It was decided at least one logged session of therapy was required to be considered a 'treatment episode' for the purposes of analysis. Only two cases were identified as having re-presented for three separate 'treatment episodes', which were discounted for consistency of analysis. The final sample list, consisting of 82 clients, was anonymised and inputted into an Excel data file. Additional data extracted from IAPTus at this stage included demographic variables (gender, age and ethnicity) and clinical variables (primary and secondary diagnoses, number of sessions and pre and post-treatment PHQ-9 and GAD-7 scores).

2.4 Questionnaires

In order to supplement the data collected from IAPTus, two different questionnaires were developed to collect data pertaining to each client's treatment episode from the therapists' perspective (see Appendix A and B). One version was dedicated to collecting data about the first treatment episode, and another about the second treatment episode. It was necessary to have two versions since often it was the case that different therapists had treated the same client at different times. Questions included asking therapists to rate the usefulness of the treatment, to provide reasons for the first episode ending and the second one beginning and to give their opinion about whether having the same therapist was useful. Both questionnaires were sent to three clinicians for piloting before being fully deployed, in order to flag up potential problems. Suggested amendments included defining reasons for treatment ending such as "failure to engage". Most questions required

fixed choice responses (usually 'yes/no/don't know') and some allowed a more open, qualitative response.

2.5 Data Collection

Questionnaires were distributed via e-mail to all high intensity therapists who remained employed by the service. In order for therapists to correctly identify clients and provide answers about their treatment accordingly, the relevant IAPTus numbers were inserted at the top of each copy of questionnaire. Once the completed questionnaires were sent back, each question response was coded and data was transferred into the anonymised Excel data file.

3.0 RESULTS

3.1 Descriptive Statistics

3.1.1 Demographics

The final sample analysed consisted of 82 cases, 23 of which were male (28%) and 59 of which were female (72%). A simple frequency calculation showed that, with regards to age split, the largest group were aged 25-34 (n=32, 39%), followed by those aged 35-44 (n=29, 35.4%). The smallest group consisted of those aged 65+ (n=1, 1.2%). In terms of ethnicity, the same frequency calculation showed that the largest group were categorised as White (n=59, 72%), followed by those categorised as Black or Black British (n=14, 17.1%). The pie charts below (Figure 2, Figure 3 and Figure 4) show the age, sex and ethnicity percentages for the sample analysed for this project, in comparison to a sample of those discharged from IAPT over a three month period. The comparison indicates that the demographic profile of the project sample was quite similar to that of overall IAPT sample. The main differences were that the project sample consisted of a higher proportion of females (72% vs 62%), a higher proportion of clients aged 35-44 (35% vs 25%) and a higher proportion of clients categorised as White (72% vs 65%).

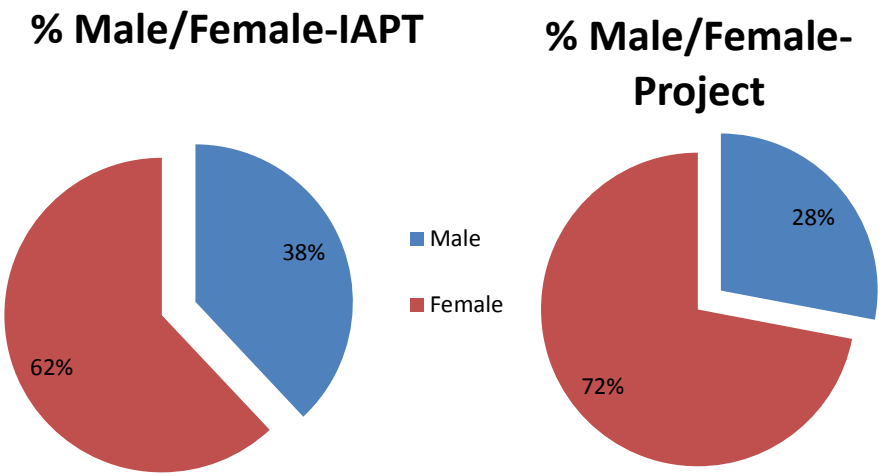

Figure 2. Pie charts showing the male/female ratio of the project sample (those who re-presented for step-3 treatment at IAPT between September 2009 and July 2012) compared to a representative sample of IAPT users

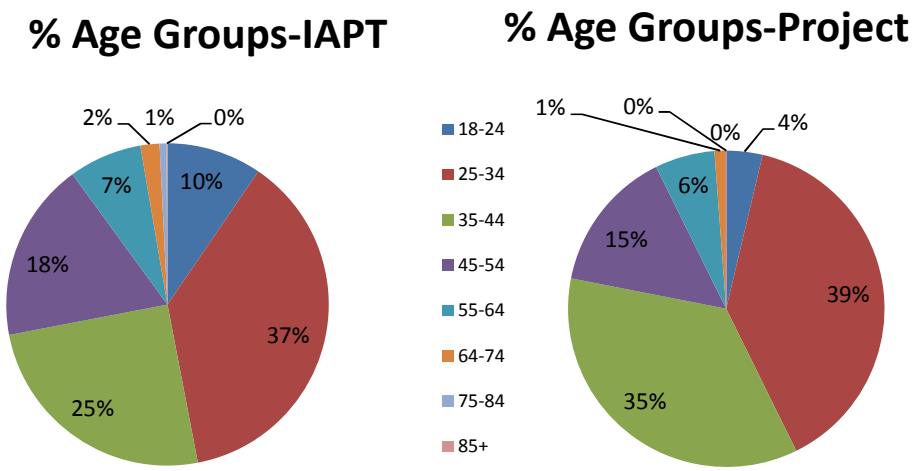

Figure 3. Pie charts showing age groups of the project sample (those who re-presented for step-3 treatment at IAPT between September 2009 and July 2012) compared to a representative sample of IAPT users

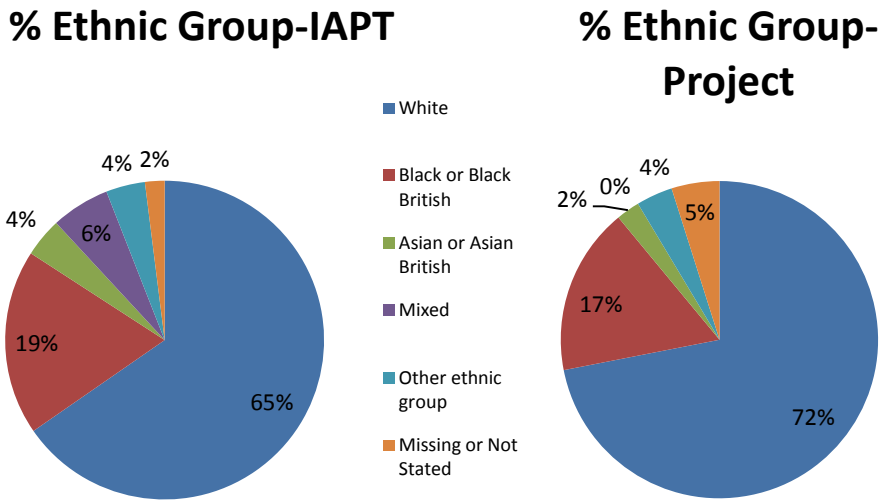

Figure 4. Pie charts showing ethnicities of the project sample (those who re-presented for step-3 treatment at IAPT between September 2009 and July 2012) compared to a representative sample of IAPT users

3.1.2 Clinical data

Table 1 below gives a summary of the clinical data collected, including the most common primary and secondary diagnoses, the mean average number of sessions, the mean pre and post-treatment PHQ-9 and GAD-7 scores, the mean average PHQ-9 and GAD-7 score changes, the percentage of those who reached 'caseness' and finally, the percentage of those who recovered. 'Caseness' was defined as a score of ten or above on the PHQ-9 or a score of eight or above on the GAD-7. For a client to be considered as 'recovered', it was necessary for both post-treatment scores to be below 'cut-off' (i.e., below ten on the PHQ-9 and below eight on the GAD-7). 'Recovery' is an important issue for IAPT services because it is a key performance requirement of the services, with every service being monitored against a target of 50% of clients moving from above to below 'caseness' over the course of treatment. The table displays the differences between the clinical variables for the 'first episode' and 'second episode' data sets. Notably, the second treatment episodes had a lower number of sessions that the first (11 versus 13), started with slightly lower PHQ-9 and GAD-7 scores and consequently had smaller PHQ-9 and GAD-7 score changes. The second episode data set had a slightly higher 'recovery rate' than the first (45.1% versus 41.5%), although the lower number of clients who reached the criteria for 'caseness' in the second episode (92% versus 98%), could account for this difference (those who did not reach 'caseness' could not technically 'recover' which meant the relative proportion of clients in the sample reaching criteria for recovery was inflated).

Further analysis showed 44% of the client sample was given the same diagnosis in their first and second episodes, which means 56% had a different diagnosis and so were treated for a different disorder in their second treatment episode.

Table 1. Clinical data split into first and second episode data sets

	First Episode	Second Episode
Most common primary diagnosis	Depressive episode (25.6%)	Depressive episode (24%)
Most common secondary diagnosis	Personality Disorder/Traits (3.7%)	Recurrent depressive disorder and Personality Disorder/Traits (both 4%)
Mean number of sessions (SD)	13.4 (7.3)	10.8 (6.1)
Mean pre-treatment PHQ-9 (SD)	16.0 (6.3)	14.7 (6.6)
Mean post-treatment PHQ-9 (SD)	10.0 (7.0)	9.8 (6.6)
Average score change PHQ-9 (SD)	-6.1 (7.3)	-4.8 (6.6)
Average pre-treatment GAD-7 score (SD)	14.7 (4.5)	13.4 (4.9)
Average post-treatment GAD-7 (SD)	9.1 (5.9)	9.2 (5.4)
Average score change GAD-7 (SD)	-5.7 (6.4)	-4.2 (6.0)
% 'caseness'	98%	92%
% recovered	41.5%	45.1%

3.1.2 Therapist data

Frequency calculations indicated that the most common reason for first treatment episode ending was "natural end with symptom improvement" (49%). The same reason was the most common given for the second treatment episode ending (38%) and there was a higher percentage of 'drop outs' in the second episode (16%) than in the first episode (13%) (see Figure 5). The profile splits of therapist 'usefulness' ratings were very similar across both episodes, with the majority reporting a "significant positive difference", (38% for first episode and 44% for second episode; see Figure 6). The main reason for offering an additional episode of treatment was "original symptoms continuing or worsening" (62%) followed by "presented with new problem" (32%; see Figure 7). This is in contrast to the diagnosis data from IAPTus which indicates the majority of clients were given a different diagnosis in the second

episode. 48% of second treatment episodes definitely involved a 'new therapeutic element'; of those who had the same therapist for the second episode, 32% thought this made a significant positive difference (although largely this was not applicable); and of those therapists treating a client for a second episode, 54% thought more CBT would be helpful.

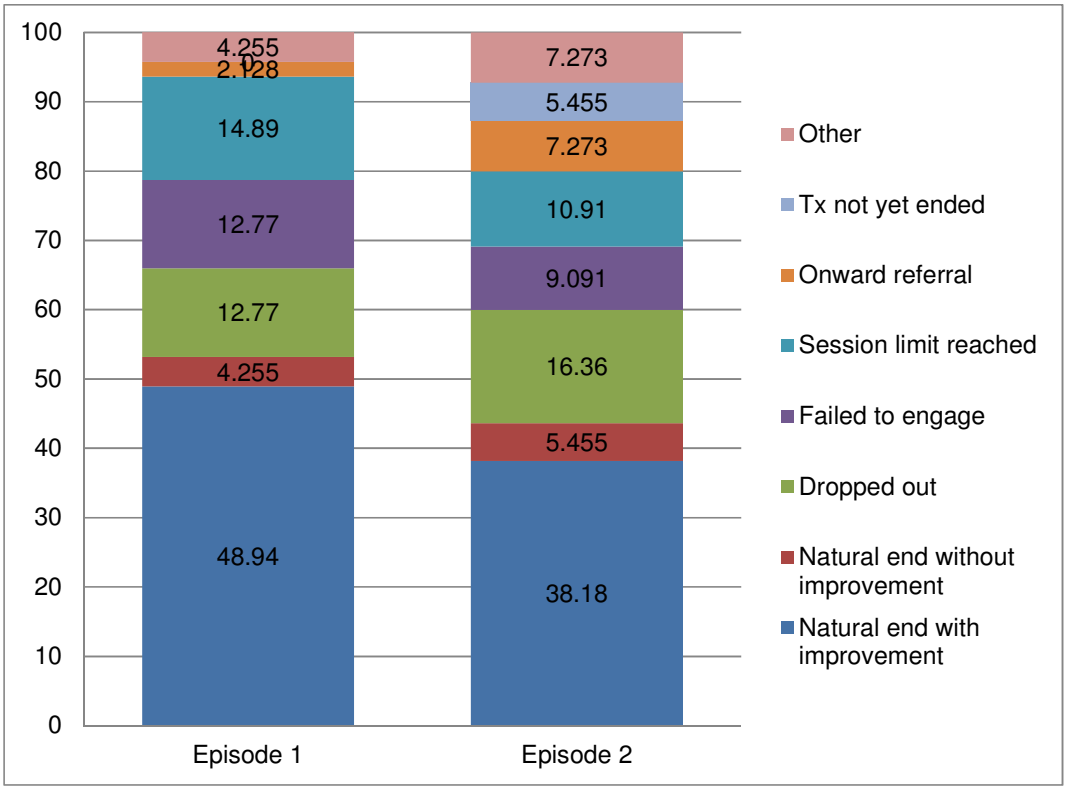

Figure 5. Bar chart showing split of reasons for first and second treatment episodes ending

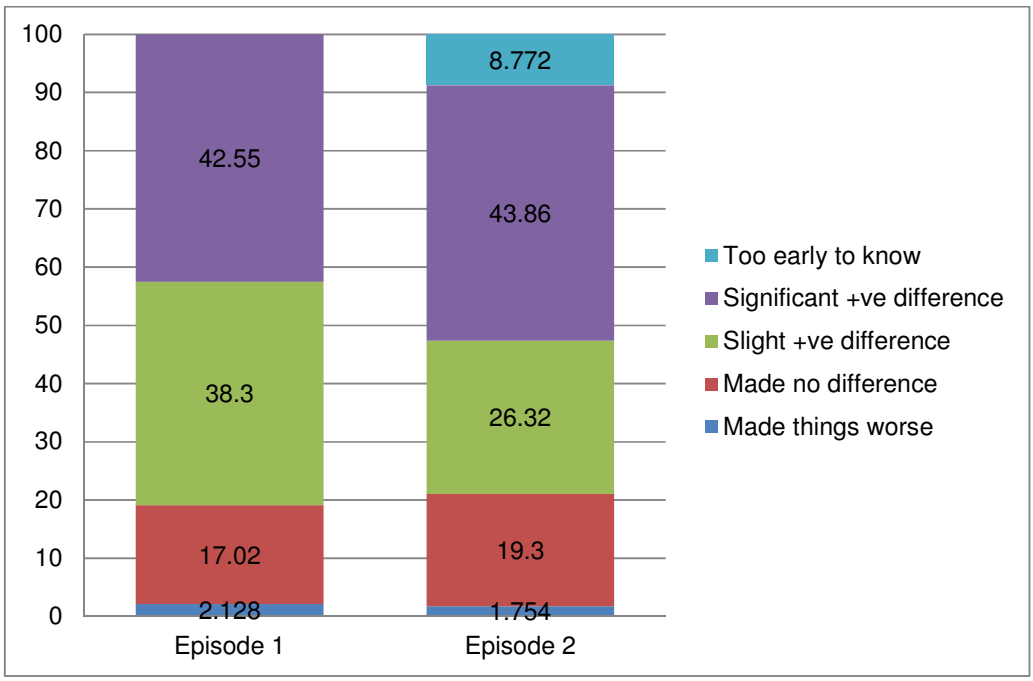

Figure 6. Bar chart showing split of therapist ratings of usefulness for first and second treatment episodes

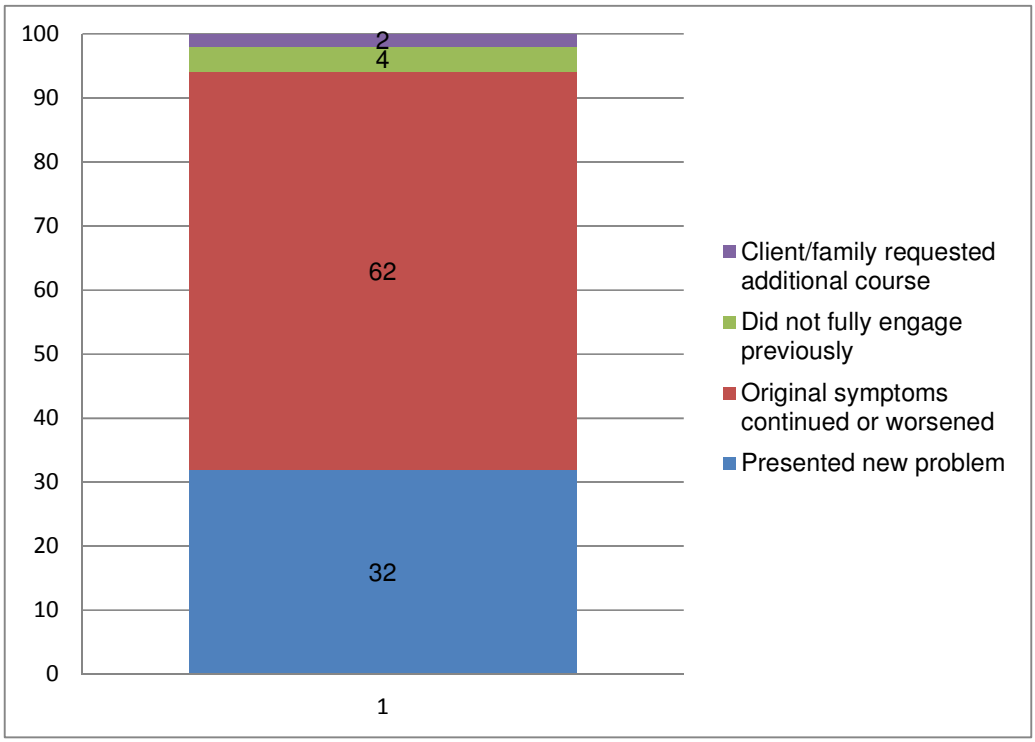

Figure 7. Bar chart showing split of reasons for offering additional treatment

3.2 Main analysis

3.2.1 Recovery groups

In order to determine how to differentiate between clients recovering and those not recovering in the second treatment episode, the sample was divided into the following groups in relation to the patterns of recovery:

1. Those that recovered on both episodes (R,R)
2. Those that did not recover on either episode (NR,NR)
3. Those that recovered on the first episode but did not recover on the second (R,NR)
4. Those that did not recover on the first episode but recovered on the second (NR,R)

A small number (n=10) were discounted for this analysis as they did not reach the criteria for 'caseness' on either the PHQ-9 or GAD-7 measures, and therefore did not meet criteria for recovery. It is possible they may have reached 'caseness' on additional anxiety measures (e.g., those measuring phobias) but this data was not collected. Table 2 below shows the number of clients in each recovery group.

Table 2. The frequency and percentages of clients in each 'recovery group'

		Frequency	Valid Percent
Valid	**Recover, Recover (R,R)**	14	19.4
	Not recovered, Not recovered (NR,NR)	28	38.9
	Recovered, Not recovered (R,NR)	15	20.8
	Not recovered, Recovered (NR,R)	15	20.8
	Total	72	100.0
Missing	System	10	
Total		82	

Table 2 shows that, of the clients who did recover the first time, 14 out of 29 (about 50%) recovered the second time and that, of the clients who did not recover the first time, 15 out of 43 (35%) recovered the second time. When split this way, the largest group was the 'NR,NR' group (n=28, 39%). This group represents those clients who did not seem to significantly benefit from treatment either initially or when repeated. Table 3 below compares the clinical data for the 'NR,NR' group with the 'NR,R' group. Notably, the average second episode pre-treatment PHQ-9 and GAD-7

scores are higher for the 'NR,NR' group. The average first episode post-treatment PHQ-9 and GAD-7 scores are also higher for this group. In addition, the second episode mean score changes for the 'NR,NR' group are extremely low (just -0.75 for PHQ-9 and -0.74 for GAD-7).

Table 3. Clinical data showing differences between first and second episodes within the 'NR.NR' and 'NR,R' groups

	NR,NR group		**NR,R group**	
	Ep 1	**Ep 2**	**Ep 1**	**Ep 2**
Most common primary diagnosis	Depressive episode (32.1%)	Depressive episode (21.4%)	Depressive episode and GAD (both 20%)	Depressive episode (26.7%)
Mean number of sessions (SD)	13.1 (7.9)	12 (5.9)	12.3 (9.3)	12.7 (5.9)
Mean pre-treatment PHQ-9 (SD)	18.9 (4.7)	17.6 (5.4)	14.8 (5.4)	14.4 (6.0)
Mean post-treatment PHQ-9 (SD)	15.4 (6.1)	12.4 (4.9)	12.7 (4.2)	6.0 (3.1)
Average score change PHQ-9 (SD)	-3.4 (5.3)	-0.75 (4.6)	-2.07 (5.9)	-8.33 (5.1)
Mean pre-treatment GAD-7 score (SD)	16.6 (3.1)	15.1 (3.5)	13.9 (4.4)	13.1 (5.0)
Mean post-treatment GAD-7 (SD)	14.6 (4.1)	14.2 (4.0)	11.5 (3.9)	5.1 (1.7)
Average score change GAD-7 (SD)	-2.07 (4.7)	-0.74 (4.7)	-2.4 (5.3)	-8.0 (5.3)

3.2.3 T-tests

In order to distinguish any variables which could identify those likely to recover in the second episode, following a lack of recovery in the first, independent samples t-tests were performed to examine whether any differences between the continuous variables for the 'NR,NR' and 'NR,R' group were significant. The results showed that the first episode pre-treatment PHQ-9 score was significantly higher for the

'NR,NR' group (M=18.9, SD=4.7) than the 'NR,R' group (M=14.8, SD=5.4; t(41)=2.61, p=.013).The first episode pre-treatment GAD-7 score for the 'NR,NR' group (M=16.6,SD=3.1) was significantly higher than the 'NR,R' group (M=13.9,SD=4.4; t(41)=2.36, p=.023. Finally, the first episode post-treatment GAD-7 score was significantly higher for the 'NR,NR' group (M=14.6, SD=4.1) than the 'NR,R' group (M=11.5, SD = 3.9; t(41)=2.36, p = .023). Therefore, the three variables which significantly differentiated these two groups were first episode pre-treatment PHQ-9 score, pre-treatment GAD-7 score and post-treatment GAD-7 scores.

3.2.4 ROC curve analysis

A ROC curve was calculated using the first episode post-treatment GAD-7 scores to see whether an acceptable "cut off point" could be achieved on the GAD-7 measure which could help predict whether a client is likely to recover in the second episode, and therefore give one indicator of the predicted usefulness of offering further treatment. A ROC curve plots the true positive rate (sensitivity) against the false positive rate (100-specificity) for different cut-off points on a particular measure. The area under the curve (AUC) relates to the discriminating accuracy and predictive ability of the measure.

Figure 8 below shows the ROC curve which plots sensitivity versus specificity for all the possible cut-offs on the GAD-7 (a score of 7 or above denotes 'caseness' and 21 is the maximum possible score). The AUC of the ROC curve can be considered 'fair' at 0.715 (SE=0.08; 95% CI=0.56-0.84, p<0.01).

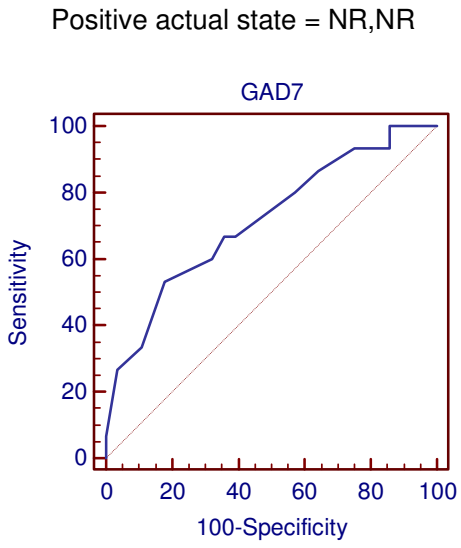

Figure 8. ROC Curve plotting possible cut-offs for first episode GAD-7 measure

Table 4. Operating characteristics of GAD-7 cut-off points

GAD-7 score (more than or equal too)	Sensitivity	Specificity	Positive Predictive Value (PPV)	Negative Predictive Value (NPV)
8	26.67	96.43	63.55	84.93
9	33.33	89.29	63.97	70.13
10	53.33	82.14	70.00	69.26
11	60.00	67.86	69.22	58.48
12	**66.67**	**64.29**	**71.89**	**58.48**
13	80.00	60.71	70.71	56.14
14	86.67	42.86	73.96	51.35
16	93.33	35.71	78.03	50.42
17	93.33	25.00	83.24	48.42
19	93.33	14.29	73.96	45.09
20	100	14.29	100	46.81

Table 4 displays the operating characteristics of the GAD-7 cut-off points from 8 to 21. The sensitivity score refers to the probability that, for someone who has the characteristic being measured, the test result will be positive (i.e., true positive rate, expressed as percentage). In this case, the figure represents the probability that those who will not recover in the second episode, will score more than or equal to a set cut-off score on the GAD-7 (or be in the 'NR,NR' group). Specificity refers to the probability that, for someone who does not have the characteristic being measured, the test result will be negative (i.e., true negative rate, expressed as percentage). In this case, this figure represents the probability that those who recover in the second episode, will score below the set cut-off score of the GAD-7 (or be in the 'NR,R' group).Two other quantities that are also often used in association with sensitivity and specificity are positive predictive value (PPV) and negative predictive value (NPV), which are also displayed in the table. PPV indicates that, if the test is positive, the likelihood that the person has the characteristic being measured. In this case, it relates to the likelihood that those who score more than or equal to a cut-off on the GAD-7, will not recover in the second episode. Following on from this, NPV

indicates that, if the test is negative, the likelihood that the person does not having the characteristic being measured. In this case, it relates to the likelihood of those who score less than the cut-off on the GAD-7, will recover in the second episode.

The choice of an optimal cut off value is usually informed by an attempt to maximise the difference between sensitivity and 1-specificity, but is difficult in this case due to the high amount of overlap between the scores. If the GAD-7 is to be used as a screening measure, a high PPV is preferable (in order to rule out those who are unlikely to recover and retain those who are likely to do so). Therefore, according to the table, a cut-off of 12 would be preferable as it has relatively good sensitivity (64.3%) and specificity (66.7%) as well as a PPV of 71.9%, meaning it is a good way of predicting those who will not recover in the second episode. However, it has a NPV of 58.5% which means it is less good at predicting those who will recover in the second episode. Since the service operates with an approach of including clients on the basis of capacity to benefit, rather than excluding them based on rigid criteria, it would not support a cut-off measure that would potentially exclude clients who could benefit.

3.3 Subsidiary Analyses

Chi-square analyses were also conducted in order to compare the categorical variables (i.e., yes/no answers) which yielded no significant differences when comparing the four 'recovery groups'. This was partly due to the small numbers in each group which meant the analysis lacked the power required. However, when collapsed into two groups instead of four (those who did recover versus those who did not recover in the second episode), a significant difference was found between the groups for therapist opinion about the helpfulness of further CBT, $X2$ (2, n=82) = 11.51, p = .003. The 2-by-2 cross-tabulation results indicated that significantly more therapists thought that more CBT would be helpful for those who recovered in the second treatment, than those who did not.

Further analysis was conducted to examine the relationship between the therapist usefulness ratings and the clinical variables. Although the small sample violated the 'minimum expected cell frequency' for a valid chi-square calculation, some interesting trends were found. In the first episode data set, there was a significant relationship between therapist usefulness ratings and mean score change in PHQ-9 (but not pre or post-treatment PHQ-9 scores, or GAD-7 scores), $X2$ (63, n=82) = 94.41, p = .006. Figure 9 shows a boxplot which provides a visual representation for the pattern of scores. The pattern of median scores (represented by the middle line

in each box) indicates that the higher the PHQ-9 score change, the higher the rating of usefulness. There were no significant relationships found between therapist usefulness ratings and other clinical variables measured.

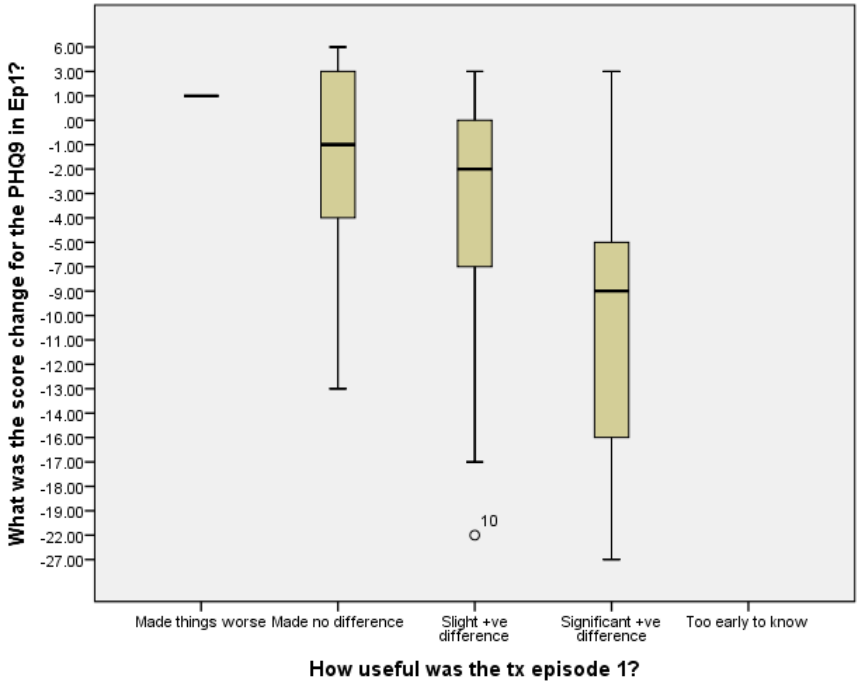

Figure 9. A box plot showing the relationship between mean score change for PHQ-9 (episode 1) and therapist usefulness ratings.

Analysis of the second episode data set showed a different trend. There was a significant relationship between therapist usefulness ratings and the post-treatment PHQ-9 score, $X2$ (88, n = 82) = 115.43, p = .270. Figure 10 shows a box plot which provides a visual representation of the pattern of scores. The pattern of median scores indicates that the lower the post-treatment PHQ-9 score, the higher the therapist rating of usefulness. There were no significant relationships found between therapist usefulness ratings and the other clinical variables measured.

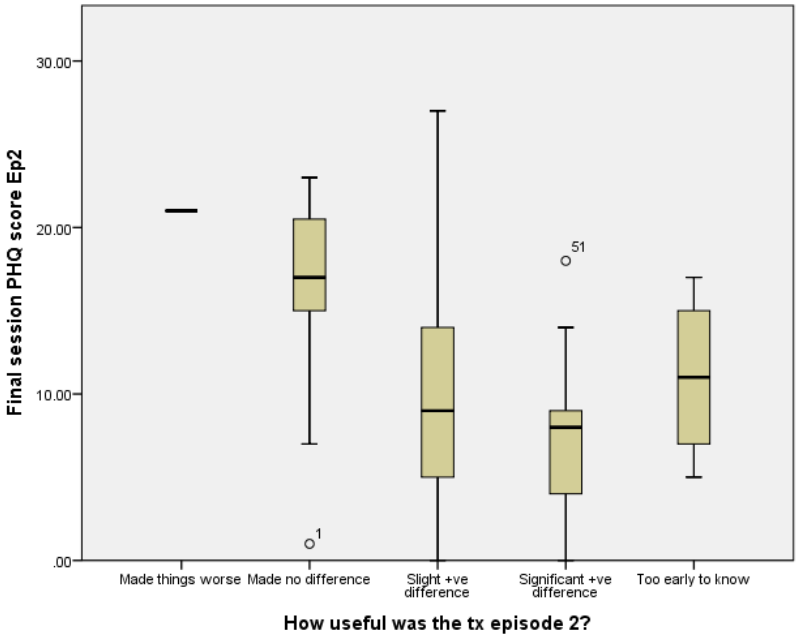

Figure 10. A box plot showing the relationship between the post-treatment PHQ-9 score (episode 2) and therapist usefulness ratings

Finally, no significant differences were found between data sets for those who had the same therapist in their second treatment, and those who had a different therapist.

3.4 Qualitative Data

The questionnaires allowed for collection of some qualitative data with regards to different factors which contributed to the therapist-rated usefulness of the treatment, and factors which may have prevented the clients from returning to IAPT for more therapy. In terms of factors which were thought to be associated with a positive treatment outcome, some of the 'client factors' included willingness to engage in the CBT approach, level of motivation to change, awareness of the benefits of CBT and socialisation to the model. 'Therapist factors' included tailoring treatment to individual problems, being flexible, having specialist knowledge or experience and having a thorough understanding of the formulation and ability to explain this clearly to the client. Some 'treatment factors' included having a strong therapeutic bond and a focus on relapse prevention (for example ensuring the client is learning how to approach potential problems, rather than be provided with solutions once the problem has occurred). Finally, in terms of the possible prevention of additional

treatment, many therapists believed that this would not have been possible due to the client presenting with a different problem when they returned for treatment, the interference of social factors such as employment or child care, and clients not following their 'blueprint'. This final point was especially important with clients who suffered from anxiety disorders which require on-going behavioural experiments and an appreciation of the importance of safety behaviours. In addition, several therapists mentioned that the clients' personality traits meant that they either required longer-term treatment or were not willing to become their 'own therapist' due to dependency issues. Some suggested options for potential prevention of additional treatment included a longer initial treatment episode, more long-term follow-up sessions, and engagement with the community or a mutual support group.

3.5 Dissemination of Findings

The findings of this audit were initially presented at a clinical leads meeting in July 2013. Following this, a briefer version of the presentation was used to disseminate findings to the wider team during a whole team meeting in October 2013.

4.0 DISCUSSION

4.1 Summary of Findings

The results of this audit show that approximately 82 clients returned to Lambeth IAPT for an additional episode of step-3 treatment between September 2009 and July 2012. The demographic profile of the sample analysed was found to be generally quite similar to that of the overall sample of clients treated by IAPT with the majority being female, between the ages of 25 and 34 and of white ethnicity. Comparison of the clinical data from the first and second episode data sets, shows that the most common diagnoses were very similar, with most clients being given a primary diagnosis of 'depressive episode'. Interestingly, when a secondary diagnosis was given, the most common was 'personality disorder' or traits of personality disorder, although for the second episode, 'recurrent depression' also featured highly. Although the sample was too small to provide much useful information in terms of diagnosis breakdown, 56% of the sample was given a different diagnosis in their second episode. This could mean that slightly over half the sample did not have their main problem identified in the first episode of treatment, or that they suffered from co-morbid disorders which were not fully recognised at initial assessment and therefore were not included in the formulation. The additional clinical data comparison shows that the first episode data set had a slightly higher average number of sessions (13 versus 11) and higher pre-treatment PHQ-9 and GAD-7 scores. The post-treatment scores were the same for both data sets. This meant that the average score changes for the PHQ-9 and GAD-7 measures were higher for the first episode than second episode, although a slightly higher proportion recovered in the second episode (45%) than in the first (42%). In other words, clients tended to have higher depression and anxiety scores when first entering the service, which meant the score reduction during initial treatment was high. However, when returning for further treatment, clients tended to begin with lower depression and anxiety scores, and therefore had a lower score reduction but were more likely to 'recover' (i.e., finish with both post-treatment scores below cut-off).

The therapist data indicated that the reasons for ending both first and second episodes were encouraging, with the most common reasons being "natural end with symptom improvement". This result correlated with the 'usefulness' data which showed most therapists rated the treatment as making a "significant positive difference" to the client. Interestingly, the overall outcomes were rated slightly more

positive for the second episode than for the first. This also correlates with the clinical data showing a slightly higher recovery rate in the second episode. The most common reason for offering a second episode was “original symptoms continuing or worsening”, followed by “client presented with a new problem”. Taken together with the diagnosis data, this could infer that original symptoms identified in the first episode were re-triggered, or returned in a slightly different form, which perhaps warranted a different diagnosis. One would expect the diagnoses give in the second episode to be slightly different and favour those which depict a chronic status, for example “recurrent depression’ rather than “depressive episode” or “GAD” rather than “panic disorder”.

Dividing the sample into ‘recovery groups’ provided way of identifying any factors which could account for differences in recovery rates, and therefore further information to determine whether the second treatment was useful. Of the 72 clients grouped according to recovery, a relatively large proportion did not recover on either episode. According to the therapist data for this group, the reason given for ending the first episode was less likely to be “natural end with improvement” and the reason for offering further treatment was more likely to be “original symptoms continued or worsened”. Although these differences were not significant, they could imply that the clients unlikely to benefit from either episode are less likely to engage fully first time round, or that an incident or change in circumstances occurs which ends the first episode pre-maturely. This could also account for the fact that this group were more likely to re-present due to their original symptoms continuing or becoming worse, since they did not engage in the first episode well enough to have sufficient impact on their original symptoms. In terms of clinical data, further analysis is needed on a larger sample to be able to determine an accurate cut-off point on GAD-7 but overall, the results imply that the higher the final GAD-7 score, the less likely clients are to recover when returning for more ‘step 3’ CBT treatment.

4.2 Clinical Implications

The results of this audit provide some interesting clinical implications. Following the first treatment episode, high levels of anxiety, rather than depression, were predictive of a lower probability of recovery during the second episode. One hypothesis for this could be linked to the effectiveness of CBT for anxiety disorders. A number of controlled trials and meta-analyses have demonstrated strong effect sizes of CBT for many anxiety disorders; including social phobia (Feske & Chambless, 1995), OCD (Abramowitz, 1997), PTSD (Bradley, Greene, Russ, Dutra

& Westen, 2005) and GAD (Borkovec & Ruscio, 2000) and it is thought to be particularly efficacious for panic disorder (Chambless & Gillis, 1993). However, some studies have suggested that the treatment efficacy for GAD and PTSD is not as strong as that of other anxiety disorders (e.g., Brown, Anthony, & Barlow 1995, Norton, Asmundson, Cox & Norton, 2000). Therefore, one could speculate that short-lived anxiety symptoms, such as panic attacks, are highly responsive to CBT techniques and likely to be reduced to a non-clinical level when treated using this approach, either during initial or repeated treatment. However, persistent anxiety symptoms such as 'worry' (a key feature of GAD), could be considered more difficult to successfully eradicate with short-term CBT. This means that the continued presence of GAD-like symptoms following an initial CBT treatment episode could be indicative of a lack of suitability to the CBT approach, which would explain the low rate of recovery following a second treatment. However, it would be unjustified to base a service change on this hypothesis since the GAD-7 simply assesses symptoms of generalised anxiety. Specific anxiety measures would need to be used to further explore this relationship.

Another interesting theoretical point highlighted by the diagnoses data and qualitative therapist responses from this audit, was that a relatively large proportion of clients who failed to recover in either their first or second episode, were noted to have features of personality disorder, or other co-morbidities. It is widely known that a high proportion of clients with a principal anxiety disorder, also meet criteria for at least one additional anxiety or mood disorder (Brown & Barlow, 1992). In their review, Mennin and Heimberg (2000) conclude that the presence of co-morbid diagnoses can interfere with the treatment of panic disorder, and that personality psychopathology in particular, has a detrimental effect on treatment outcome. They suggest this is due to the fact that clients with comorbid disorders challenge the implementation of manualized treatments as they may behave quite differently to those presenting with one primary disorder. Furthermore, Durham, Swan and Fisher (2000) explain that when a client presents with co-morbidity, the tasks of developing a formulation and treatment plan are more complex and demanding for the therapist and that such clients are likely to require more intensive therapy and more careful follow-up.

This audit also highlights the fact that clients with suspected Personality Disorder (PD) or traits of the disorder can present their own unique challenges. PD is frequently described as likely to contribute towards risk of relapse and poor recovery, but confusion concerning the definition means that such outcomes lack

validity (Segal et al, 2003). Some researchers have proposed that PD can be difficult to treat successfully due to the construct of neuroticism. Individuals scoring highly on measures for this trait tend to amplify shame, worry and interpersonal sensitivity (Kendler, Neale, Kessler, Heath & Eaves, 1993). Other researchers advocate that the perceived criticism aspect of expressed emotion by significant others, is another related construct of PD which creates barriers to successful treatment outcomes in CBT (Butzlaff & Hooley, 1988). Individuals with PD are often thought to be better suited to longer-term psychotherapy as they are more likely to have a complex history, attachment issues and related interpersonal difficulties, which makes it more difficult for them to form a strong therapeutic alliance and therefore benefit from a short-term intervention (Parry & Richardson, 1996).

4.3 Service Implications and Recommendations

The results showed that, of those who return for more treatment, about 45% recovered in the second episode, which indicates that further treatment can often be helpful. Therapists were likely to rate treatment episodes as useful, regardless of whether it was a first or second episode, and endings tended to be because there was natural symptom improvement. The majority of clients were offered further treatment because they presented with a new problem, however, further information from the questionnaires inferred that clients would present with different symptoms linked to the same disorder, or with a co-morbid problem which had not been discovered in the first treatment. This implies that it is important for therapists to conduct a thorough assessment at the beginning of treatment in order to determine the presence of any co-morbid disorders or symptoms, so that these can be fully integrated into the formulation. The recent expansion of primary care services such as IAPT means that the service is likely to receive more referrals for severe, chronic and complex cases, with a higher probability of personality traits being present. Successful treatment of such clients may therefore require an even more enhanced focus on relapse prevention with the use of booster sessions, longer-term follow-ups or extended episode lengths.

More generally, the implications of the audit findings highlight the difficulty for primary care services to strike the right balance between efficiency and effectiveness. As the audit shows, clients with more severe, complex or chronic problems (e.g., PD, GAD and co-morbidities) are more likely to return for treatment and many do not recover. This creates a dilemma since although offering these clients a CBT intervention through IAPT may be efficient, it may not be the most

effective option of treatment in the long-term. In addition, pressure to accept a large number of complex referrals may lead therapists to spend a long time attempting to engage clients with little aptitude or motivation and therefore spend too little time working with those who are motivated and prepared for therapy. (Durham, Swan & Fisher, 2000). Looking forward, the new phase of IAPT is hoping to continue increasing access of evidence-base psychological treatments to the wider population, but we might ask the question "at what cost?" This audit supports the need to consider adapting and adjusting services to ensure they can accommodate client needs at an idiographic level, rather than assume a "one size fits all" approach.

Finally, on a more practical level, it may be beneficial for the IAPTus system to become equipped so it is able to label those clients who have been seen for a second or third 'treatment episode' which meets the criteria specified in this audit (i.e., more than one assessment session and not counting those as part of a group or for employment advice). This would make it easier and less time consuming to produce similar audits in the future.

4.4 Methodological Limitations

Despite the interesting results, this audit did suffer from several methodological limitations. Firstly, it was difficult to gain significant results from many of the statistical tests, particularly when comparing differences between the four smaller 'recovery groups' on the therapist data. This was due to a large percentage of missing data and resultant lack of power. Many of the therapists who had treated clients in the sample, had left the service within the period specified for analysis, and about a quarter of questionnaires e-mailed to therapists were not returned. Although clinical data was more easily obtained due to routine collection via the IAPTus system, there were some problems with the accuracy of the search results. For the purposes of the study, an 'episode' related to 'more than one session of CBT treatment with a step-3 therapist'. However, many of the clients listed in the search output had 'episodes' registered on the system which related to alternative criteria. Therefore, data had to be double-checked for each client listed which was time-consuming. On a broader epistemological level, one of the main aims of the study was to verify the "usefulness" or effectiveness of the second treatment episodes. One could argue that simply measuring usefulness via score change on objective symptom measures is rather reductionist, and fails to consider a number of extraneous variables which could have a significant impact on outcome, such as

previous therapy, personality traits, family history or client expectations. In reality, reasons for returning for therapy and the perceived usefulness of therapy are complex and multi-factorial.

The questionnaires themselves could also be subjected to criticism. Since the therapists were keen to provide a holistic view of each client's treatment, some found it difficult to quantify their opinions using categorical responses. For example, the answers to the question about factors contributing to perceived 'usefulness' of the episode, which gave the option of 'therapist', 'client' and 'treatment' factors, was limited in use for quantitative analysis. This was due to the fact that many therapists gave answers which fitted with more than one factor since they are inextricably linked. Such therapeutic or process factors are difficult to define objectively and can vary according to individual interpretation. This was also a limitation when asking the therapists to consider whether the treatment used a "new therapeutic element". The subjectivity and biased nature of the questionnaires can also be applied to the symptom measures upon which 'recovery' is based (i.e., the PHQ-9 and the GAD-7). One could argue this method for measuring 'recovery' is more service than client-centred, and fails to consider the broad range of factors which are integral to a client's overall well-being. "Reasons for ending" and "returning for treatment" are also wide-ranging, and open to subjectivity.

The answers to the therapist questionnaires were contingent upon the therapists' memory of the clients in question, many of whom were treated over a year prior to the study. Furthermore, a few therapists commented that the fact the questionnaires were focussing on reasons for clients returning, and possible ways of preventing their return, implied they had failed as therapists and discounted the potential positive aspects of clients re-presenting for further treatment. Since many of the clients who did not recover in the first episode, did in fact recover in the second, this indicates that a re-referral to IAPT can often lead to a positive outcome.

4.5 Conclusions and Areas for Future Study

Responding to the original aims, the results of the audit conclude that clients return for treatment usually because their original symptoms continue, worsen or take on a slightly different form and that about 40% recover on return for more treatment. Therefore, the additional treatment offered to clients in the time-span measured, could be considered to be useful (according to service policy and therapist opinion). Post-treatment scores on the GAD-7 measure were associated with usefulness, but this relationship needs further analysis to warrant any broad service changes.

The findings offer wide scope for future research. It would certainly be useful to collect data using specific anxiety disorder measures to further understand the relationship between anxiety levels throughout the course of therapy and levels of CBT-responsiveness. It may also be worth repeating a similar analysis after a few years, in order to obtain a larger sample which would give higher power for statistical analyses, and perhaps collect data on additional variables such as risk levels and complexity (e.g., history of abuse) as well as information about whether clients had been 'stepped up' from low intensity level. It may also be of interest to compare the sample from this audit to those who completed one episode of treatment in the same period, in order to establish differences in clinical variables and ways of predicting the likelihood of being re-referred for more treatment. It may be useful to collect data via responses from clients, as well as therapists, in order to investigate whether the answers match in terms of perceived usefulness of treatment, and perhaps leave space for clients to suggest improvements. Finally, due to the complexity and variety of factors involved in 'usefulness' or 'efficacy' of treatment, it would be beneficial to examine these constructs with detailed qualitative analyses.

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Appendix A First episode questionnaire

FIRST EPISODE QUESTIONNAIRE

ID details of client:

1) Diagnosis (for this episode):

2) Overall, how useful do you think this episode of treatment was?

Made things worse
Made no difference
Made a slight positive difference
Made a significant positive difference

3) Why do you think this was the case? (you can underline more than one)

a) Therapist factors? (e.g., experience, competency, flexibility)

Comments:

b) Treatment factors? (e.g., suitability to CBT)

Comments:

c) Client factors? (e.g., willingness, motivation to change, personality)

Comments:

4) What was the main reason for this treatment episode ending?:

Natural end to therapy with symptom improvement
Natural end to therapy without symptom improvement
Client dropped out/declined service
Client failed to engage (e.g., repeated DNAs or cancellations)
Session limit reached
Client referred to another service
Other (please specify)

Appendix B Additional episode questionnaire

ADDITIONAL EPISODE QUESTIONNAIRE

ID Details of client:

1) Episode number:

2) Diagnosis (for this episode):

3) Thinking about your reasons for offering this client an additional episode of therapy, please tick all that apply.

Reason	Please tick	Comments/details
Client presented with a new problem		
Original symptoms continued, worsened or were re-triggered		
Lack of available alternative treatment		
Supporting client while they waited for another service		
Client did not fully engage in prior course		
Concern about risk		
Client and/or family requested additional course		
Other (please specify)		

2) Overall, how useful do you think this episode of treatment was?

Made things worse
Made no difference
Made a slight positive difference
Made a significant positive difference
Too early in treatment to know

3) Why do you think this was the case? (you can underline more than one)

a) Therapist factors? (e.g., experience, competency, flexibility)

Comments:

b) Treatment factors? (e.g., suitability to CBT)

Comments:

c) Client factors?(e.g., willingness, motivation to change, personality)

Comments:

4) Did this episode of treatment involve a new therapeutic element or technique that had not been used before?

YES / NO / UNSURE

Comments:

5) If you have seen this patient for more than one episode of treatment, how useful do you think it was for the patient to see the same therapist?

Made things worse
Made no difference
Made a slight positive difference
Made a significant positive difference
N/A

6) What was the <u>main reason</u> for this treatment episode ending?:

Natural end to therapy with symptom improvement
Natural end to therapy without symptom improvement
Client dropped out/declined service
Client failed to engage (e.g., repeated DNAs or cancellations)
Session limit reached
Client referred to another service
Treatment has not yet ended
Other (please specify)

7) Is there anything that could have prevented an additional episode from occurring? This could be something the therapist or the client could have done differently or a different service option (e.g., relapse prevention or mutual support group)?

8) Only answer if this was FINAL episode of step 3 treatment and has been completed – If this client were to re-present again for therapy, do you think more CBT would be helpful?

YES / NO /UNSURE

9) Any other comments?